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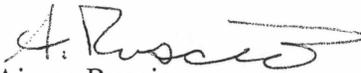
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Mindfulness and Tobacco Dependence in Cigarette Smokers: Mediating Mechanisms

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Abstract

Tobacco use remains the leading cause of preventable death in the United States. Mindfulness-based treatments may be useful in smoking cessation. Using a multiple-mediator model, the study examined negative affect (Positive and Negative Affect Schedule – Negative Affect; PANAS-NA), positive affect (PANAS - Positive Affect; PANAS - PA), perceived stress (Perceived Stress Scale; PSS), and a decentered perspective (Depression Implicit Association Test; D-IAT) as mediators of the association between mindfulness (Mindful Attention and Awareness Scale; MAAS) and tobacco dependence (Wisconsin Inventory of Smoking Dependence Motives; WISDM). Baseline data from a mindfulness-based smoking cessation trial (N = 140) were used. PANAS-PA (95% CI = -2.83, -0.39) and D-IAT (95% CI = -1.72, -0.12) were significant partial mediators. PANAS-NA (95% CI = -2.32, 0.58) and PSS (95% CI = -0.42, 3.12) were not significant mediators. Greater mindfulness may reduce tobacco dependence via two mechanisms: increasing positive affect and fostering a detached perspective.

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Mindfulness and Tobacco Dependence in Cigarette Smokers: Mediating Mechanisms

According to the 2010 US Surgeon General's Report, "Today in the United States, tobacco use remains the single largest preventable cause of death and disease for both men and women" (U.S. Department of Health and Human Services, 2010, p. i). Over 65 million (one in five) Americans smoke cigarettes (Sondik, Madans, & Gentleman, 2010). Pharmacological, motivational, and cognitive-behavioral interventions have been developed and as many as approximately 70% of smokers report the desire to quit. Yet 85% of quit attempts end in failure (Cinciripini & McClure, 1998; MMWR, 2011; U.S. Department of Health and Human Services, 2000). Researchers have turned to the study of Mindfulness Based Therapies in search of effective tobacco cessation treatments that may offer routes to tobacco cessation not currently used by conventional treatments (Altner, 2002; Bowen & Marlatt, 2009; Brewer et al., In press; Cropley, Ussher, & Charitou, 2007; Davis, Fleming, Bonus, & Baker, 2007; Gifford et al., 2004; Leigh, Bowen, & Marlatt, 2005; Rogojanski, Vettese, & Antony, 2011; Ussher, Cropley, Playle, Mohidin, & West, 2009; Vidrine et al., 2009; Waters et al., 2009).

Origins of Mindfulness

Mindfulness originated in Siddharta Gautama's, also known as the Buddha's, teachings dating from the sixth century B.C.E. in India. In these teachings, he outlined Four Noble Truths that state: (1) suffering is universal and unavoidable; (2) suffering is caused, not by experience, but by our need to have experience a certain way; (3) the cessation of suffering is possible; and (4) cessation can be achieved by practicing the Noble Eightfold Path. Right mindfulness is one element of the Noble Eightfold Path. Other elements include right view, right intention, right

speech, right action, right livelihood, right effort, and right concentration (Kumar, 2002; Teasdale & Chaskalson, 2011). The Buddhist concept of mindfulness has been defined as “bare attention...the mind is trained to remain in the present, open, quiet, and alert, contemplating the present event (Bodhi, 2011, Chapter VI).”

Conceptualizing mindfulness for Western psychologists, Brown and Ryan (2003) described dispositional mindfulness as a state of consciousness characterized by an enhanced attention and awareness to present moment experience or reality. Although mindfulness is an inherent feature of human consciousness, it can vary markedly between and within individuals, ranging from a highly mindful state to a highly habitual, automatic, or mindless state. Specifically, Brown and Ryan reported that individual differences accounted for 29% of the variation in state mindfulness over time, whereas within-person variability explained the remaining 71%. Brown and Ryan also reported that mindfulness, as measured by the Mindful Attention and Awareness Scale (MAAS), was positively associated with measures of well-being including positive affect, life satisfaction, vitality, and self-actualization. Further, mindfulness was negatively associated with anxiety and depressive symptoms. Group differences in level of mindfulness were shown between general community adults and Zen practitioners, suggesting that formal mindfulness practice may increase the measured construct of mindfulness in individuals (Brown & Ryan, 2003).

For the purpose of the current study, mindfulness was conceptualized as a form of cognitive retraining that affects attentional processes and that fosters a decentered perspective to emotional stimuli. Cognitive retraining describes the repeated performance of a cognitive

task (e.g., meditation), which results in the improvement of cognitive processes (e.g., attention or a decentered perspective). Mindfulness involves keeping the “spotlight” of attention focused on one’s internal and external experience in the present moment, precluding secondary processing of stimuli (Shapiro, Carlson, Astin, & Freedman, 2006). A decentered perspective refers to viewing negative thoughts and feelings as temporary and transient mental events rather than as valid reflections of reality or central aspects of the self (Teasdale, 2004). Taken together, maintaining attention in the present moment with a detached perspective results in changes in the subsequent processing of cognitive and affective stimuli (Waters, et al., 2009). The current study examined the effect of a decentered perspective component of mindfulness in reducing self-reports of tobacco dependence. The attentional processes component was not addressed.

Mindful vs. Mindless Processing

To explain the difference between “mindless” and “mindful” processing, compare a hypothetical “mindless” individual with a hypothetical “mindful” individual experiencing depressive thoughts and emotions. The mindless individual is riding a subway home and begins to think about a presentation that did not go well earlier in the day. He or she has thoughts such as “I should have prepared more” and “I’m such a failure.” The individual experiences feelings of worthlessness. Lacking the decentered perspective described above, he or she does not separate the contents of consciousness from his or her sense of self, resulting in an increasingly negative view of the self that exacerbates his or her depression. The individual replays the memories of the presentation, focusing on everything that did not go well. So much

of his or her attention is focused on past events that he or she does not attend to the current location of the subway train, causing the individual to miss his or her stop.

In contrast, the mindful individual experiencing similar depressive thoughts and emotions has the cognitions “I am having the thought that I should have prepared more”; “I am having the thought that I’m a failure” and “I feel worthless.” He or she identifies both thoughts and feelings as transient mental events and experiences separation between these events and his or her more stable sense of self. He or she notices the thoughts and feelings without getting caught up in ruminative thought. He or she maintains attention on what is happening in the present moment rather than on past events. He or she notices the sounds of the subway car, sights such as other people in the car or the reflection of light on the window, and other thoughts and emotions as they arise. The mindful individual can experience depressive thoughts and emotions without engaging in depressive rumination (Brown, Ryan, & Creswell, 2007; Teasdale, 2004; Waters, et al., 2009).

Mindfulness-Based Treatments and Psychopathology

In order to place the current study in a wider context, the form and efficacy of mindfulness-based treatments for a wide range of psychological disorders was reviewed. Western psychological interventions that use mindfulness-based treatments fall into two broad categories: consciousness-based treatments and skills-based treatments. Consciousness-based treatments use daily meditative practices to promote change and include Mindfulness Based Stress Reduction (MBSR) and Mindfulness Based Cognitive Therapy (MBCT). MBSR consists of an eight week course of group therapy, originally developed in 1979 to reduce stress, pain, and

illness in medical patients in a hospital setting (Kabat-Zinn, 2003). MBCT, modeled after MBSR, also consists of eight weeks of group therapy designed as a cognitive-behavioral approach for preventing relapse in depression (Teasdale et al., 2000). Skills-based treatments such as Acceptance and Commitment Therapy (ACT) and Dialectical Behavior Therapy (DBT) place emphasis on teaching mindfulness and acceptance skills, among other skills, that can be incorporated into a patient's life without daily meditative practice.

MBSR and MBCT. Consciousness-based mindfulness treatments have been reported to reduce symptoms in anxiety disorders and binge eating disorder and to prevent depressive relapse (Baer, 2003). There is evidence that mindfulness-based treatments have large effects in patients with anxiety and depressive disorders and moderate effects in patients with subclinical anxiety and depressive symptoms (Hofmann, Sawyer, Witt, & Oh, 2010). Hofmann, Sawyer, Witt, and Oh (2010) reported large pre-post effect size estimates in studies involving patients with anxiety disorders (Hedges's $g = 0.97$) and depressive disorders (Hedges's $g = 0.95$). The authors found moderate pre-post effect size estimates for anxiety symptoms (Hedges's $g = 0.63$) and depressive symptoms (Hedges's $g = 0.59$). The effect sizes reported included studies in which mood and anxiety were the targeted disorders, and studies in which MBSR and MBCT were used as an adjunct treatment in a physical illness (cancer, fibromyalgia, traumatic brain injury, heart disease, and diabetes). It is important to note that this body of research has been criticized for having a large number of uncontrolled studies (Toneatto & Nguyen, 2007).

ACT and DBT. Skills-based treatments, such as ACT and DBT, have a stronger evidence base than the pure form consciousness-based treatments, such as MBSR and MBCT. ACT was

reported to be effective for a wide range of psychopathologies, including social phobia, agoraphobia, depression, psychosis, borderline personality disorder, and trichotillomania (S. C. Hayes, Luoma, Bond, Masuda, & Lillis, 2006). ACT was demonstrated to be moderately more effective than structured interventions designed to target the problem, such as Group Cognitive Behavioral Therapy or Cognitive Therapy (Cohen's $d = 0.63$). ACT was demonstrated to be moderately to largely more effective than wait list, treatment as usual, or placebo conditions (post-treatment: Cohen's $d = 0.99$; follow-up: Cohen's $d = 0.71$). Published randomized controlled trials (RCTs) indicated the efficacy of DBT when applied to Borderline Personality Disorder (BPD), comorbid BPD and substance abuse disorder, and binge eating disorder (S. C. Hayes, Masuda, Bissett, Luoma, & Guerrero, 2004).

Mindfulness-Based Treatments and Smoking

In addition to treating psychopathology, mindfulness has been studied as a treatment for cigarette smoking cessation. Changes in cognitive and emotional processing resulting from greater mindfulness may reduce smokers' dependence on tobacco. Consider a mindless cigarette smoker attempting to quit who encounters smoking stimuli (e.g., a smoking advertisement or someone else smoking). He or she may experience the cognition "I want a cigarette" and subsequently experience craving. Without a decentered perspective, both the thought and the emotion are associated with the individual's sense of self, resulting in more craving and smoking-related cognitions and placing the individual at greater risk of relapse after cessation of smoking. In contrast, a more mindful smoker also attempting to quit smoking experiences the same smoking-related stimuli differently. The mindful smoker who is abstaining

notices the subsequent thought (“I am having the thought that I want a cigarette”) and emotion (“I am craving a cigarette, but the craving will pass”) as transient mental phenomena distinct from his or her sense of self, leaving him or her able to encounter the smoking cue with less impact on the quit attempt than the mindless smoker.

Mindfulness-based treatments for cigarette smoking have yielded promising but mixed results. Eleven studies examined mindfulness-based treatments or dispositional mindfulness in the context of smoking cessation or tobacco use and dependence. Four multi-week mindfulness-based studies, including two RCTs, showed that mindfulness-based interventions improved abstinence rates following a quit attempt (Altner, 2002; Brewer et al., 2011; Davis et al., 2007; Gifford et al., 2004). Four studies of the effect of brief mindfulness-based interventions on smoking behavior, affect, and withdrawal symptoms did not yield a clear pattern of results (Bowen & Marlatt, 2009; Cropley et al., 2007; Rogojanski et al., 2011; Ussher et al., 2009). Two cross-sectional studies of dispositional mindfulness showed negative associations with dependence and negative affect, and positive associations with positive affect and a decentered perspective (Vidrine et al., 2009; Waters et al., 2009). In contrast, one cross-sectional study of dispositional mindfulness reported positive correlations between dispositional mindfulness and self-identifying as a smoker (vs. non-smoker) and self-identifying as a binge-drinker (vs. non-binge drinker) (Leigh et al., 2005). The literature is promising; however, large, well-controlled studies are lacking. Also, studies providing information about mechanisms of action are needed to determine when and for whom mindfulness meditation may be an effective treatment. Table 1 contains a summary of the pertinent literature.

Multi-week mindfulness interventions. Two RCTs provide evidence that multi-week mindfulness- or acceptance-based treatments result in higher abstinence rates when compared with pharmacological or behavioral interventions (Brewer et al., 2011; Gifford et al., 2004). Brewer et al. (2011) randomly assigned 88 treatment-seeking, nicotine dependent adults to Mindfulness Treatment (MT) or the American Lung Association's Freedom From Smoking (FFS) intervention. Both groups attended eight hour-and-a-half sessions, twice-weekly over the course of four weeks. The MT group (vs. FFS) displayed greater reductions in cigarette use, a trend towards greater abstinence rates immediately following treatment, and significantly greater abstinence rates at the 17-week follow-up (Brewer et al., 2011). Gifford et al. (2004) reported robust effects of an ACT intervention (vs. NRT) for smoking cessation in an RCT (N = 76). The intervention consisted of seven weeks of group and individual therapy. The authors reported significantly greater abstinence rates at one year in the experimental group (vs. NRT)(Gifford et al., 2004). Taken together, the RCTs provide evidence of the efficacy of mindfulness- and acceptance-based treatments when compared to both behavioral (FFS) and pharmacological interventions. In both cases, the interventions were superior to control conditions consisting of active treatments.

Two additional studies showed increased abstinence rates following multi-week mindfulness-based interventions; however, these studies lack the methodological rigor of an RCT (Altner, 2002; Davis et al., 2007). Altner (2002) presented a controlled, non-randomized longitudinal study (N = 117) of the effectiveness of MBSR when used as an adjunct to nicotine replacement therapy (MBSR + NRT vs. NRT) in a workplace smoking intervention. MBSR

consisted of a standard eight week course. NRT consisted of nicotine patches, nicotine gum, and/or nicotine nasal spray. The author reported lower abstinence rates in the MBSR+NRT group at 15 months than in the NRT group (MBSR + NRT = 32.6% vs. NRT = 24.6%); however, no test of statistical significance was used to examine the difference (Altner, 2002). Davis, Fleming, Bonus, and Baker (2007) reported the results of an uncontrolled nonrandomized pilot study (N=18) of MBSR in a community sample. Achieving a 55% point prevalence abstinence rate at six weeks, they concluded that MBSR was a promising intervention that warranted further inquiry (Davis et al., 2007).

Brief mindfulness interventions. Brief mindfulness interventions have also been studied in the context of smoking (see Table 1). Four studies provide contradictory evidence of the effect of an urge-surfing technique (Bowen & Marlatt, 2009; Rogojanski et al., 2011) or a body-scan (Cropley et al., 2007; Ussher et al., 2009) on smoking behavior, nicotine dependence, withdrawal symptoms, and negative affect.

Two studies provided mixed evidence for the efficacy of an “urge-surfing” technique. The urge surfing intervention used in both studies coached participants to picture urges and cravings as waves and to attend to and “ride” their normal fluctuations during a cue-exposure exercise lasting approximately 20 minutes. Bowen and Marlatt (2009) reported reductions in cigarettes smoked per day over the course of seven days following the intervention. They reported negative (null) findings for negative affect and urges; however, mindfulness was a significant moderator of the association between negative affect and urges (Bowen & Marlatt, 2009). In an attempt to replicate Bowen and Marlatt (2009), Rogojanski et al. (2011) reported a

study with a very different pattern of results. In contrast to Bowen and Marlatt (2009), Rogojanski et al. (2011) did not find an effect of urge-surfing on cigarettes smoked per day; however, they did show reduced negative affect following the intervention. Similar to Bowen and Marlatt (2009), they showed no difference in urges following the intervention. Additionally, they reported that the intervention reduced nicotine dependence and symptoms of depression (Rogojanski et al., 2011). The differences in the patterns of results reported preclude definitive conclusions concerning the efficacy of urge-surfing as an intervention.

Another brief mindfulness exercise, a body scan, has been examined for use in reducing withdrawal symptoms. Similar to the urge-surfing technique, two studies reporting contradictory results have been published. A body scan is a guided relaxation routine that instructs participants to pay attention to the sensations they feel (pain, fatigue, heat, cold, tightness, relaxation, etc.) throughout their bodies. Cropley, Ussher, and Charitou (2007) presented the results of an RCT (N = 30) of the efficacy of a ten-minute “body scan” (vs. control, listening to a natural history passage) in reducing tobacco withdrawal symptoms and strength of desire to smoke. The intervention (vs. control) significantly reduced strength of desire to smoke, but did not significantly reduce irritability, tension, or restlessness (Cropley et al., 2007). Ussher, Cropley, Playle, Mohidin, and West (2009) examined the effects of a similar ten-minute “body scan” (BS) (vs. isometric exercise [IE], control [listening to a natural history passage]; N = 48) on withdrawal symptoms in the laboratory and in the natural environment. Both BS and IE (vs. control) resulted in significant or marginally significant reductions in strength of desire to smoke, irritability, restlessness, tension, difficulty concentrating, and stress in either the

laboratory or the natural environment. Taken together, the studies do not provide a clear pattern of results.

Studies of brief mindfulness interventions did not offer a clear pattern of results. Two studies provided support for brief mindfulness interventions reducing smoking behavior with an urge-surfing intervention (Bowen & Marlatt, 2009) and withdrawal symptoms with a body scan (Ussher et al., 2009). In contrast, two studies did not find significant effects for urge-surfing on smoking (Rogojanski et al., 2011) or a body scan on withdrawal symptoms (Cropley et al., 2007). The benefit of brief mindfulness based interventions for smokers remains unclear.

Dispositional mindfulness. Three cross-sectional studies examined associations between dispositional mindfulness and smoking behavior or risk factors for smoking relapse. Vidrine et al. (2009) documented a negative association between dispositional (or trait) mindfulness and dependence on tobacco, such that more mindful individuals were less dependent on tobacco. Additionally, they reported that dispositional mindfulness was negatively associated with withdrawal and positively associated with agency (confidence in one's ability to cope during high-risk situations without relapse). Waters et al. (2009) reported that dispositional mindfulness was positively associated with positive affect and a decentered perspective to depression-related stimuli and negatively associated with perceived stress, negative affect, and symptoms of depression. Taken together, the two studies provide a pattern of associations that suggests that dispositional mindfulness should be beneficial to smokers trying to quit (Vidrine et al., 2009; Waters et al., 2009).

Leigh, Bowen, and Marlatt (2005) provided exceptions to these positive findings. In a

cross-sectional analysis of mindfulness, smoking, binge-drinking, and spirituality, Leigh and colleagues found that mindfulness was positively associated with being a smoker (vs. being a non-smoker) in a college sample (Leigh et al., 2005).

The literature reviewed contained the promising finding of increased abstinence rates in several studies of multi-week mindfulness-based interventions (Altner, 2002; Brewer et al., 2011; Davis et al., 2007; Gifford et al., 2004). At the same time, drawing definitive conclusions from these data is premature due to small sample size (Davis et al., 2007) and lack of experimental controls and/or randomization (Altner, 2002; Davis et al., 2007). The majority of the evidence from cross-sectional studies of dispositional mindfulness and smoking behavior, nicotine dependence, and risk- and protective-factors during a quit attempt provide positive evidence (Vidrine et al., 2009; Waters et al., 2009), with one notable exception (Leigh et al., 2005). Studies of the effect of brief mindfulness-based interventions on cigarette smoking behavior, negative affect, and symptoms of withdrawal did not yield a clear pattern of results. Compelling but methodologically limited evidence exists for the benefit of multi-week mindfulness-based interventions and dispositional mindfulness.

Mindfulness and cigarette smoking: Mechanisms. While there was evidence supporting the effect of mindfulness-based treatments on cigarette-smoking behavior, mechanisms explaining how mindfulness training produced results were not clearly identified. The literature reviewed yielded one formal study of a mechanism explaining the effect of mindfulness-based interventions on cigarette smoking behavior (Gifford et al., 2004). Gifford et al. (2004) examined negative affect, withdrawal symptoms, and avoidance and inflexibility as possible

mediators of the relationship between condition and smoking outcomes. Negative affect and withdrawal symptoms are pathways targeted by NRT. Level of avoidance and inflexibility, the pathway targeted by ACT, was measured via self-report and described the use of avoidant strategies towards internal experiences and inflexible links between internal experiences and relapse. Endorsing the beliefs that negative affect invariably leads to smoking and that one must avoid negative affect is one example of avoidance and inflexibility. Avoidance and inflexibility was a significant partial mediator of the association between group and smoking outcome. Participants in the ACT group had lower avoidance and inflexibility scores, which resulted in higher rates of abstinence at one year (Gifford et al., 2004).

The results from several other studies suggested possible mechanisms of action that were not formally tested. Rogojanski et al. (2011) reported that urge-surfing reduced negative affect. Ussher et al. (2009) reported that a ten-minute body scan reduced withdrawal symptoms, including desire to smoke, irritability, restlessness, tension, difficulty concentrating, and stress. Waters et al. (2009) reported that dispositional mindfulness was positively associated with positive affect and a decentered perspective to depression-related stimuli and negatively associated with perceived stress, negative affect, and symptoms of depression.

While previous studies provide preliminary insight into possible mechanisms of action, a comprehensive analysis investigating mechanisms that explain the effect of mindfulness on cigarette smoking behavior or dependence has yet to be conducted. Project Mind was planned to fill the gap in the literature. Project Mind used Mindfulness-Based Therapy for Smoking Cessation, a new treatment modeled after Mindfulness-Based Cognitive Therapy, to investigate

the effect of the treatment on abstinence rates at 26 weeks post-quit day and to examine mechanisms of change. The study consisted of a pilot study (N = 158) that provided baseline data and a main study (N = 400) that consisted of a longitudinal randomized-controlled trial. Both phases of the study were conducted at the University of Texas, M.D. Anderson Cancer Center with Dr. David Wetter serving as Principal Investigator.

Using the baseline data from the Project Mind pilot study, Vidrine et al. (2009) documented a negative association between dispositional mindfulness, measured with the Mindful Attention and Awareness Scale, and dependence on cigarettes, measured with the Wisconsin Inventory of Smoking Dependence Motives, such that more mindful individuals were less dependent on tobacco. The purpose of the current study was to examine positive affect, negative affect, perceived stress, and a decentered perspective as mediators of the negative association between mindfulness and dependence. Baseline data from the Project Mind pilot study were used to conduct preliminary analyses.

Negative Affect, Stress, and Smoking

Negative affect and perceived stress were hypothesized to partially explain the association between dispositional mindfulness and cigarette dependence. Negative affect was defined as “a general dimension of subjective distress and unpleasurable engagement that subsumes a variety of mood states including anger, contempt, guilt, fear, and nervousness” (Tomkins, 1963; Watson, Clark, & Tellegen, 1988, p. 1063). Perceived stress describes “the degree to which situations in one’s life are appraised as stressful” (Cohen, Kamarck, & Mermelstein, 1983, p. 385). There is some evidence of a moderate association between

negative affect, stress, and cigarette smoking relapse. Specifically, Shiffman, Paty, Gyns, Kassel, and Hickcox (1996) reported that acute increases in negative affect preceded approximately 30% of smoking lapses during a quit attempt. Testing the hypothesis that negative affect increases lapses by increasing smoking-cue reactivity, Shiffman and Gwaltney (2008) reported that negative affect increased the likelihood of smoking temptations and lapses during a quit attempt, independent of the presence or absence of smoking cues. In a review of the smoking, stress, and negative affect literature, Kassel, Stroud, and Paronis (2003) reported that smoking status (smoker vs. non-smoker) covaried with stress, negative life events, and negative affect. They also found evidence that smokers increase smoking in response to laboratory stressors and negative life events.

Positive Affect and Smoking

Positive affect was hypothesized to partially explain the mindfulness-dependence association. Positive affect has been described as “the extent to which a person feels enthusiastic, active, and alert” (Tomkins, 1962; Watson, et al., 1988, p. 1063). While the association between negative affect, stress, and smoking is well-established, less information is available on the role of positive affective states and smoking. Both intravenous and smoking administration of nicotine resulted in mild euphoriant or positive hedonic effects (Glautier, 2004; Pomerleau & Pomerleau, 1992; Soria et al., 1996). Dvorak and Simon (2008) reported that compared to non-users, daily tobacco users reported less positive affect in a college sample. Leventhal (2010) reported that reinforcement smoking, a tendency to smoke to regulate affect, moderated the relationship between positive affect and urge to smoke.

Smokers high in reinforcement smoking (vs. smokers low in reinforcement smoking) evinced a significant negative association between positive affect and urge to smoke. To summarize, positive affect was negatively associated with daily smoking (Dvorak & Simon, 2008). Further, in participants who tended to smoke to regulate affect, positive affect was negatively associated with desire to smoke (Leventhal, 2010), suggesting that positive affect may play an important role in smoking behavior and dependence.

Decentered Perspective and Smoking

Mindfulness practice enhances a decentered perspective to negative affective stimuli. S.C. Hayes et al. (2004) described this phenomena as a “shift from ‘self as content’ (the self is an object in consciousness) to ‘self as context’ (the self is observing the objects in consciousness and is not the object itself)” (S.C. Hayes et al., 2004, p. 273). A decentered perspective to smoking and negative affective stimuli may reduce smokers’ dependence on tobacco by increasing their tolerance for negative affective or smoking related cues, enabling them to experience but not react to these cues.

Waters et al. (2009) examined the associations between mindfulness and a decentered perspective to smoking-related stimuli, depression-related stimuli, and anxiety-related stimuli. Only a decentered perspective to depression-related stimuli was significantly positively associated with mindfulness. One explanation for the finding is that the decentered perspective developed with mindfulness, while theorized to be broad-based, is in reality specific to depressive stimuli. Another potential explanation is that mindfulness engenders a more global decentered perspective that was not captured by the measures used by Waters et al. (2009).

While questions remained regarding the findings, the study marked the first use of an implicit cognitive task to attempt to measure a decentered perspective (Waters et al., 2009).

Mediation

Mediation analyses are widely used to test mechanisms, addressing questions of how and why variables are related. Preacher and Hayes (2008, p. 879) defined the method as “the process by which some variables exert influence on others through intervening or *mediator* variables” (MacKinnon, 2008; Preacher & Hayes, 2008).

Simple mediation analyses. Simple mediation analyses study the effect of a causal variable X on an outcome variable Y when mediated by a single variable M (see Figure 1). The total effect of X on Y is represented by path c and may be quantified by regressing Y onto X . A simple mediation analysis partials the variance in Y explained by X into an indirect effect (path $a*b$) of X on Y through M and the direct effect (path c') of X on Y . Path a describes the effect of X on M . Path b describes the effect of M on Y while controlling for X . The paths are commonly represented by unstandardized regression coefficients. The paths are additive such that $c = c' + a*b$ (Preacher & Hayes, 2008).

Multiple mediation analyses. Multiple mediation analyses expand the method described above to simultaneously test multiple mediating variables (see Figure 2). The total effect of X on Y (path c) is partialled into the direct effect (path c') and several specific indirect effects (path a_1*b_1 , path a_2*b_2 , path a_3*b_3 , and path a_4*b_4). While four mediators are depicted in Figure 2, multiple mediation models may be designed to test any number of mediators. As with single mediators, the specific indirect effects and the direct effect when added equal the

total effect ($c = c' + a_1*b_1 + a_2*b_2 + a_3*b_3 + a_4*b_4$) (Preacher & Hayes, 2008).

Multiple mediator models offer several advantages over testing single mediators separately. Multiple mediation analysis affords the opportunity to test both the total effect of a group of variables as well as testing the variables individually as mediators. Second, testing multiple mediators allows the researcher to determine the extent to which M mediates the association between X and Y, while controlling for the effect of other mediators included in the model. Third, testing multiple mediators reduces the likelihood of parameter bias because of omitted variables. Omitted variable errors occur when a separate variable not included in the model causes both the mediator and the outcome variable. Fourth, a multiple mediator model allows comparison of the relative magnitudes of specific indirect effects. This comparison is especially useful when different theories posit different mediators (Preacher & Hayes, 2008).

Mediation studies in the psychological sciences largely follow Baron and Kenny's (1986) guidelines for detecting mediation statistically. The guidelines outline four steps that may be tested using multiple regression analyses that, when met, allow the researcher to logically infer an indirect effect. Baron and Kenny (1986) also recommended using the Sobel test (Sobel, 1982) to estimate the size of the indirect effect. The Sobel test involves calculating a z-statistic that represents the indirect effect. Fritz and MacKinnon (2007) reported that over 70% of mediation studies published in two prominent psychology journals, the *Journal of Consulting and Clinical Psychology* and the *Journal of Applied Psychology*, followed Baron and Kenny's recommendations. While influential and widely used, the method has been criticized for being poorly powered under certain circumstances and for incorrectly assuming normality in the

distribution of indirect effects (Fritz & MacKinnon, 2007). More powerful statistical methods for testing mediation have been developed since Baron and Kenny (1986), including resampling methods and methods that use asymmetric distributions to test the significance of indirect effects (Fritz & MacKinnon, 2007; Shrout & Bolger, 2002).

The current study used four different methods to test mediation: (1) Baron and Kenny's (1986) causal steps approach; (2) the Sobel test (1982) of the indirect effects; (3) PRODCLIN (distribution of the **PROD**uct Confidence Limits for **IND**irect effects), a program that computes confidence limits for the product of the a and b path (MacKinnon, Fritz, Williams, & Lockwood, 2007); (4) bias-corrected bootstrapping, a resampling method that estimates confidence limits around the indirect effect (Preacher & Hayes, 2008).

Specific Aims and Hypotheses

Specific Aim 1: To examine negative affect, positive affect, perceived stress, and a decentered perspective as mediators of the relationship between mindfulness and cigarette dependence.

Hypothesis 1.1: The effect of mindfulness on cigarette dependence will be significantly partially mediated by negative affect, while controlling for positive affect, perceived stress, and a decentered perspective.

Hypothesis 1.2: The effect of mindfulness on cigarette dependence will be significantly partially mediated by positive affect, while controlling for negative affect, perceived stress, and a decentered perspective.

Hypothesis 1.3: The effect of mindfulness on cigarette dependence will be significantly partially mediated by perceived stress, while controlling for negative affect, positive

affect, and a decentered perspective.

Hypothesis 1.4: The effect of mindfulness on cigarette dependence will be significantly partially mediated by a decentered perspective, while controlling for negative affect, positive affect, and perceived stress.

Specific Aim 2: To examine four different methods of conducting mediational analyses using the causal steps approach, the Sobel test, PRODCLIN, and bias-corrected bootstrapping.

Methods

The Parent Study

The current study consists of analyses of baseline data collected during a larger cigarette smoking cessation trial. The purpose of the parent study was to use a two group Randomized-Controlled Trial (RCT) to develop and evaluate a Mindfulness-Based Treatment (MBT) for nicotine dependence using a group format. Participants were recruited from the Houston, TX metropolitan area. The parent study was approved by the Institutional Review Board of The University of Texas, M. D. Anderson Cancer Center (Appendix B). The current study was approved by Institutional Review Board of the Uniformed Services University of the Health Sciences (Appendix B).

Inclusion/Exclusion Criteria

Inclusion criteria for the study consisted of being 18 years of age or older; a current cigarette smoker with a self-reported history of at least 5 cigarettes/day for the last year; motivated to quit within the next 30 days (preparation stage; Prochaska, DiClemente, & Norcross, 1992); a home address and a functioning home telephone number; and able to speak and read in English. Because nicotine patches were used during the parent study, participants were excluded for contraindication for nicotine patch use. Participants were excluded for current self-reported use of tobacco products other than cigarettes to maintain a sample of only cigarette smokers. Participants who used bupropion or nicotine products other than the study patches were excluded because the parent study was a treatment study. Use of other treatments during the study would have the potential to confound results. Participants who

self-reported pregnancy or lactation were also excluded in order to reduce risk to the fetuses from use of the study nicotine patches. Participants with another household member already enrolled in the study were also excluded in order to maintain a more random sample.

Research Participants

One hundred and fifty-eight participants were recruited into the study. Analyses were conducted on 140 biochemically-verified cigarette smokers (expired carbon monoxide ≥ 8 ppm) who provided data on all study assessments (see Table 2, Demographic Statistics). The sample was 58.6% Caucasian, 32.1% African American, and 9.3% Other. Approximately 11.4% of the sample self-identified as Hispanic. Forty-five percent of participants were female, while 55% were male. Participants reported an average of 13.49 years (SD = 2.45) of education and a mean age of 43.76 years (SD = 11.78). Thirty-seven percent of the sample endorsed being married or living with a significant other. Fifty-eight percent of participants reported being employed, while 31.4% reported an annual household income less than \$20,000. Individuals smoked an average of 20.40 (SD = 9.25) cigarettes a day and reported smoking for 25.00 (SD = 12.07) years.

Procedures

Participants were recruited from the greater Houston, Texas, metropolitan area between February 2005 and May 2006 as part of a pilot study for a larger clinical trial to determine the efficacy of using mindfulness based therapy for smoking cessation. Participants were screened via telephone to verify eligibility. The current study used data collected at a baseline visit prior to any clinical intervention. All self-report questionnaires were completed on

a computer. Participants did not receive compensation for the telephone interview or the baseline visit; however, they were compensated for subsequent visits that were part of the parent study and not the current study. While 158 participants were recruited into the study, data from the depression IAT (D-IAT) were not available for 18 participants. Eleven participants did not complete the D-IAT because of experimenter, computer or participant error, while data from seven could not be used (as described later). Analyses were conducted on the remaining 140 participants who provided data on all study assessments.

Measures

Mindfulness. The Mindful Attention Awareness Scale (MAAS) was used to assess mindfulness. The MAAS is a 15 item self-report questionnaire with demonstrated reliability (Cronbach's $\alpha = .82$; Brown & Ryan, 2003). Each item is rated on a six point Likert scale ranging from 1 = "almost always" to 6 = "almost never." An example item from the MAAS is "I could be experiencing some emotion and not be conscious of it until some time later" (Brown & Ryan, 2003).

As described in Brown & Ryan (2003), the MAAS total score was calculated as a mean of the 15 items with a minimum score of 1 and a maximum score of 6. Mindfulness as measured by the MAAS has been reported to correlate with several well-being constructs, discriminate between individuals who practice meditation and those who do not, and predict well-being outcomes in a clinical sample (Brown & Ryan, 2003).

Positive and Negative Affect. The Positive and Negative Affect Schedule (PANAS) was used to measure both positive (PANAS-PA) and negative affect (PANAS-NA). The PANAS was

comprised of two 10 item scales that measure positive and negative affect. The items are scored using a six point Likert scale ranging from 1 = “very slightly or not at all” to 6 = “extremely.” The PANAS asked about experiences “in the last week.” Total scores for each subscale range from a minimum of 10 to a maximum of 60, with higher scores indicating greater levels of affect. Example items include “hostile” for the PANAS-NA and “excited” for the PANAS-PA. The scales independently demonstrate adequate internal reliability, with Cronbach’s α ranging from .86 - .90 for Positive Affect and .84 - .87 for Negative Affect depending on the time period identified in the instructions. The scales are largely uncorrelated and scores demonstrated stability over a two month period (Watson & Clark, 1988).

Perceived Stress. The Perceived Stress Scale (PSS) is a 14-item scale that measures the degree to which participants perceive that their lives are stressful. Items are scored using a five point Likert scale ranging from 0 = “never” to 4 = “very often.” A four-item version of the scale was used. The four items used were those that were correlated most highly with PSS total scores. Using the 4-item version, PSS total scores range from a minimum of 0 to a maximum of 16 with higher scores indicating greater levels of stress. An example item from the PSS is “In the last month, how often have you felt that you were unable to control the important things in your life?” Internal consistency for the four-item version was reported as good (Cronbach’s α = .72, Cohen, et al., 1983).

Decentered Perspective. The Depression Implicit Attitude Test (D-IAT) is a computerized reaction time task used to assess the strength of mental associations. Specifically, participants sorted stimuli based on two concepts: “me” vs. “not me”, and “DEPRESSED” vs. “NOT

DEPRESSED”. One block of critical trials (Task 1) presents participants with the task of sorting stimuli as “DEPRESSED + me” or “NOT DEPRESSED + not me” (Figure 3). Another block (Task 2) requires participants to sort stimuli as “NOT DEPRESSED + me” or “DEPRESSED + not me” (Figure 4). As discussed below, the relative strengths of automatic mental associations can be inferred from the difference in response times on Task 1 and Task 2.

D-IAT Stimuli. Me/not me words were derived from previous IAT research (Brown & Ryan, 2003). Me words included me, mine, my, and I. Not me words included them, they, it, their, and other. The depressed words were lonely, depressed, guilty, failure, hopeless, gloomy, unhappy, discouraged, sad, and low. The not depressed words were content, joyful, happy, pleased, excited, cheerful, positive, funny, fun, and merry (Waters et al., 2009).

D-IAT Procedure. For each trial, participants were presented with a word in the center of a computer monitor (Figures 3 and 4). Participants categorized each stimulus word by pressing either the “L” key or the “R” key on the computer keyboard. Labels on the top of the screen reminded participants which two categories corresponded to the “L” and “R” key, respectively for the current trial. Instructions reminded participants to respond to each trial as quickly and accurately as possible. In three blocks (1, 2 and 5), the computer randomly presented words from the stimulus lists. In four blocks (3, 4, 6 and 7), the computer randomly presented words while alternating between a depressed/not depressed word and a me/not me word (Table 3). A correct response resulted in the presentation of the next word after an interval of 150 ms. Participants were notified of errors by a red “X” that appeared and remained below the stimulus until the response was corrected. Researchers instructed participants to correct errors

quickly (Waters et al., 2007; Waters et al., 2009).

D-IAT Scoring. Greenwald et al. (2003)'s preferred scoring algorithm was used to calculate the IAT effect (Greenwald, Nosek, & Banaji, 2003, Table 3). A difference score between mean RTs per trial on Task 1 and Task 2 was computed. The IAT effect, *D*, was computed by dividing the difference score by the pooled standard deviation of response times. The scoring reduces the correlation between *D* and overall reaction time (RT) a measure of processing speed. Assessments with response times of < 300 ms on more than 10% of the trials (7 participant assessments or 4.43% of participants) were discarded. Responding in less than 300 ms indicates that participants are responding without completing the task. All response times > 10,000 ms were also discarded. Response times greater than 10,000 ms indicate that the participant temporarily abandoned the task. Incorrect response RTs were replaced by the block mean (correct responses) + 600ms (error penalty, Greenwald et al., 2003) (Waters et al., 2007; Waters et al., 2009).

The IAT effect, captured with the IAT *D*-score, reveals whether mental associations are stronger between "DEPRESSED + me" and "NOT DEPRESSED + not me" (Task 1) compared to "NOT DEPRESSED + me" and "DEPRESSED + not me" (Task 2) (de Houwer, 2002). In the present conceptualization, stronger mental associations between "DEPRESSED + me" and "NOT DEPRESSED + not me" represent a mindless state where little distance exists between an individual's sense of self and negative (specifically depressive) contents of consciousness (see Figure 5). Stronger mental associations between "NOT DEPRESSED + me" and "DEPRESSED + not me" represent a mindful state, characterized by a decentered perspective to negative

(specifically depressive) contents of consciousness (see Figure 6; Waters et al., 2009).

Dependence. The Wisconsin Inventory of Smoking Dependence Motives (WISDM-68) is a 68 item multidimensional questionnaire that measured tobacco dependence. Items were scored using a seven point Likert scale ranging from 1 = “not true of me at all” to 7 = “extremely true of me.” The total WISDM score, calculated by summing 13 subscale scores, ranged from 13 to 91 with higher scores indicating greater levels of dependence. Example items from the WISDM include “I frequently smoke to keep my mind focused” and “Smoking helps me deal with stress.” Internal consistency for the total scale is excellent (Cronbach’s $\alpha = .97 - .99$) (Piper et al., 2004).

Data Analysis

Strategy 1. The causal steps approach involved using regression analyses to infer the existence of specific indirect effects. Given predictor variable X, possible mediators $M_1 - M_4$, and outcome variable Y, Step 1 required using regression to establish a significant path correlation between X and Y (path c). In Step 2, a significant correlation using a regression equation between X and M (path a) was established. Step 3 demonstrated that M predicts Y while controlling for X (path b). All four possible mediators were entered simultaneously during this step. Again, a regression equation was used. If the path from X to Y was reduced to zero with the addition of M (path c’), then requirements for step 4 were met and total mediation occurred. Meeting steps 1 - 3, but not step 4 indicated partial mediation (Baron & Kenny, 1986).

The causal steps approach has several strengths, including being the most widely used and recognized test of mediation. Yet, there are two major limitations to the method. The

causal steps approach is poorly powered when the direct effect of X on Y is small ($c' \leq 0.14$). Additionally, the causal steps approach infers but does not provide an estimate of the indirect effect in the population. With a significant c path (Step 1), a path (Step 2), and b path (Step 3), a researcher can infer that an indirect effect of X on Y through M_1 must exist; however, the researcher cannot estimate the indirect effect, and subsequently is unable to test the statistic for significance (Fritz & MacKinnon, 2007; A. F. Hayes, 2009).

Strategy 2. The Sobel (1982) test provides the estimate of the indirect effect that the causal steps approach lacks. Using the path coefficients derived from the analyses described above, multiplying the a path coefficient by the b path coefficient and dividing by an estimate of the standard error of $a*b$ yields an estimate of $a*b$ in the form of a z-statistic. The z-statistic may then be used to test the null hypothesis that $a*b$ is equal to zero in the population. While the Sobel test is also widely used and recognized, it also has limitations. The test is poorly powered. Additionally, because the Sobel test is a z-statistic, it assumes normality in the sampling distribution of $a*b$; however, this assumption is routinely violated. When $a*b$ does not equal zero, sampling distributions of $a*b$ are skewed and have excess kurtosis (Fritz & MacKinnon, 2007; A. F. Hayes, 2009; MacKinnon et al., 2007).

Strategy 3. PRODCLIN was used to compute confidence limits for the indirect effect based on the distribution of the product of the a and b paths. Values of α (a path regression coefficient), β (b path regression coefficient), δ_α (a path standard error), δ_β (b path standard error), and ρ (correlation between α and β) can be used to calculate confidence intervals based on a standard normal distribution using ± 1.96 for critical values. The distribution of the indirect

effect is seldom normal. Simulation studies have verified that confidence intervals derived from a standard normal distribution are often inaccurate. PRODCLIN provides confidence intervals based on the asymmetric distribution of the product of two standard normal variables, using tables of critical values determined by the value of α , B , δ_{α} , and δ_B (MacKinnon et al., 2007). Values of α , B , δ_{α} , and δ_B were obtained during the Strategy 1, causal steps analyses. The null hypothesis for this test is that the indirect effect through each mediator is equal to zero; therefore, the null hypothesis was rejected for any confidence interval that did not contain zero.

Strategy 4. The study used a resampling procedure to estimate confidence intervals around the indirect effect. While PRODCLIN uses critical values from a previously derived and static distribution of the product of two standard normal variables, bootstrapping involves creating a unique distribution of the indirect effect from the experimental data. Five thousand estimates of the indirect effect were calculated, each by drawing a sample of $N=140$ with replacement from the dataset. Ninety-five percent confidence intervals were calculated from the sampling distributions obtained. The confidence intervals were corrected for bias resulting from skew in the sampling distribution, yielding bias-corrected confidence intervals. The null hypothesis for this test is that the indirect effect through each mediator is equal to zero; therefore, the null hypothesis was rejected for any confidence interval which does not contain zero (MacKinnon et al., 2007).

All four methods of analysis were repeated with age and sex entered as covariates. Age was correlated with mindfulness such that older people had higher levels of mindfulness ($r =$

.25, $p = .003$). Sex was correlated with tobacco dependence such that females had higher levels of dependence ($r = .16$, $p = .05$). Race, marital status, education level, employment status, household income, cigarettes smoked per day, and expired carbon monoxide level were not correlated with the independent or dependent variable under investigation in this study and were therefore not included as covariates.

The study used SPSS Version 18 for Strategy 1, the causal steps approach. An online calculator available at <http://www.people.ku.edu/~preacher/sobel/sobel.htm> was used for Strategy 2, the Sobel test (Preacher, 2010). The study used the PRODCLIN R macro downloadable from <http://www.public.asu.edu/~davidpm/ripl/Prodclin/> for Strategy 3 (MacKinnon, n.d.). PRODCLIN macros are also available for SAS or SPSS. For Strategy 4, bias-corrected bootstrapping, the study used a SAS macro available from <http://www.afhayes.com/spss-sas-and-mplus-macros-and-code.html#indirect> (A. F. Hayes, n.d.).

Power Analysis

The power of a test to detect an indirect effect is a function of both the test itself and the magnitude of the a path, the b path, and the c' path in the population. Generally speaking, power is maximized when the b path is somewhat larger than the a path (Kenny, 2009). Also, analyses based on asymmetric sampling distributions of the indirect effect tend to be more powerful than analyses that use symmetric distributions of the indirect effect (A. F. Hayes, 2009).

Fritz and MacKinnon (2007) reported necessary sample sizes to achieve 80% power for

common tests of mediation based on simulations. If the a and b path coefficients (expressed as standardized regression coefficients) are small to medium ($a = 0.26$, $b = 0.26$), then the causal steps approach requires a sample size of 158 (if $c' = 0.59$) to provide 80% power to detect a mediation effect. With the same small to medium a and b path coefficients, the Sobel test requires a sample size of 196, PRODCLIN requires a sample size of 161, and bias-corrected bootstrapping requires a sample size of 148. Other sizes of the a and b path yield a similar pattern of results. Bias-corrected bootstrapping emerged as the most powerful method of analysis. When the direct effect is medium to large (c' path $\geq .39$), the causal steps approach and PRODCLIN are comparable and the Sobel test is the least powerful approach. When the direct effect is small ($c' \leq 0.14$), the causal steps approach is poorly powered. In this case, PRODCLIN is the second most powerful test after bias-corrected bootstrapping, the Sobel test is the third most powerful, and the causal steps is the least powerful.

Previous research revealed a correlation between mindfulness and positive affect, negative affect, and perceived stress (Waters, et al., 2009). Correlations between mindfulness and positive affect ranged from $r = .30$ to $.39$. Correlations between mindfulness and negative affect ranged from $r = -.39$ to $-.43$. Brown & Ryan (2003) reported a correlation between mindfulness and perceived stress of $r = -.46$. While these data can be used to estimate the a path of our analyses, a review of the literature did not reveal appropriate data for estimating the b or c' path.¹

Because the study used an existing data set, the sample size was limited to $N = 140$. Previous studies indicated that the a path for the mediators tested in this study may be

expected to range from the absolute value of $r = \pm .3$ to $\pm .46$ (Brown & Ryan, 2003). While the b path cannot be estimated from the literature, Fritz and MacKinnon's (2007) analyses revealed that, for bias-corrected bootstrapping, there was close to 80% power if $a = 0.26$ and $b = 0.26$. PRODCLIN, another analysis used, was less powerful than bias-corrected bootstrapping, comparable in power to the causal steps, and more powerful than the Sobel test (Fritz & MacKinnon, 2007). The study was marginally underpowered, increasing the likelihood for a type II error (not rejecting the null hypothesis when it is false in the population). The combination of using more powerful tests and replicating results using four different methods mitigated the power limitations of a pre-determined sample size.

Results

Descriptives

Data from 140 participants were used in the primary analyses. The descriptive statistics for this sample are presented in Table 4. MAAS scores, PA scores, and PSS scores were not significantly different from the samples with which the measures were normed (Brown & Ryan, 2003; Cohen et al., 1983; Watson et al., 1988). NA scores were higher ($t [1140] = 5.82, p < .001$) in this sample than in the normative sample, which constitutes mildly elevated levels of negative affect (Watson et al., 1988). WISDM scores were elevated in the study sample compared to the normative sample ($t [1209] = 3.61, p < .001$); however, the difference while statistically significant is not clinically relevant (Piper et al., 2007). Both the study sample and the normative sample scores indicated moderate dependence on cigarettes. A normative sample was not available for the depression IAT (D-IAT).

Completers vs. Non-completers

The study compared the D-IAT completers ($n = 140$) to the D-IAT non-completers ($n = 18$) on all demographic statistics and major variables used in the study analyses to gain confidence that the two groups were equivalent. No significant differences were found between completers and non-completers on demographic statistics (Table 5). Additionally, no significant differences were found between completers and non-completers on MAAS, PANAS-NA, PANAS-PA, PSS, D-IAT, or WISDM scores (Table 6).

Mediational Analyses

The significant total effect of the MAAS on the WISDM ($B = -4.27 [1.19], p < .001$)

appears in Figure 7. Examining the regression equation reveals that for every one standard deviation increase on the MAAS, predicted WISDM scores decrease by -4.27 units, approximately one third of a standard deviation. The association between MAAS scores and WISDM scores was of moderate magnitude ($r = -0.27$, $p = .001$). The results of the four analyses conducted for each mediator are summarized in Table 7.

Negative Affect. Using Strategy 1, analyses revealed a robust effect of the MAAS on the PANAS-NA ($B = -3.90$ [.68], $p < .001$); however the path between PANAS-NA and the WISDM, while controlling for the MAAS, PANAS-PA, the PSS, and the D-IAT was not significant ($B = 0.23$ [.17], $p = .19$). Because criteria for Step 3 were not met, we conclude that the PANAS-NA is not a significant mediator of the relationship between MAAS scores and WISDM scores.

The Sobel test (Strategy 2), PRODCLIN (Strategy 3), and bias-corrected bootstrapping (Strategy 3) revealed similar results to Strategy 1. Using the Sobel test, multiplying the a_1 and b_1 path coefficients resulted in an indirect effect of $a_1 * b_1 = -0.90$. Dividing $a_1 * b_1$ by an estimate of the standard error of $a_1 * b_1$ yielded a nonsignificant z-statistic ($z = -1.30$, $p = .19$). PRODCLIN yielded 95% Confidence Intervals with a point estimate of $a_1 * b_1 = -0.90$, a lower bound of -2.31 and an upper bound of 0.38. Bias-corrected bootstrapping resulted in a point estimate of $a_1 * b_1 = -0.88$ bounded by a lower bound of -2.32 and an upper bound of 0.58 (95% CI [-2.32, 0.58]). Because both the PRODCLIN and bias-corrected bootstrapping confidence intervals contain zero, we do not reject the null hypothesis that $a_1 * b_1 = 0$ in the population and conclude that PANAS-NA is not a significant mediator of the association between MAAS scores and WISDM scores, using both Strategy 3 and Strategy 4.

Positive Affect. Using Strategy 1, the causal steps approach, we found the direct effect of the MAAS on the WISDM to be significant ($B = -4.27 [1.19]$, $p < .001$), passing Step 1. Analyses revealed a robust effect of the MAAS on the PANAS-PA ($B = 2.50 [.75]$, $p = .001$). Likewise, the path between PANAS-PA and the WISDM, while controlling for the MAAS, PANAS-NA, the PSS, and the D-IAT, was significant ($B = -0.50 [.15]$, $p = .002$), passing Step 3. We concluded that the PANAS-PA was a significant partial mediator using the causal steps approach.

The Sobel test (Strategy 2), PRODCLIN (Strategy 3), and bias-corrected bootstrapping (Strategy 3) revealed similar results to Strategy 1. Using the Sobel test, multiplying the a_1 and b_1 path coefficients resulted in an indirect effect of $a_2 * b_2 = -1.24$. Dividing $a_2 * b_2$ by an estimate of the standard error of $a_2 * b_2$ yielded a significant z-statistic ($z = -2.32$, $p = .02$). PRODCLIN yielded a point estimate of $a_2 * b_2 = -1.25$ and 95% confidence intervals with a lower bound of -2.43 and an upper bound of -0.37. Bias-corrected bootstrapping resulted in a point estimate of $a_2 * b_2 = -1.23$ bounded by a lower bound of -2.83 and an upper bound of -0.39 (95% CI [-2.83, -0.39]). (See Figure 8 for the distribution of 5,000 bootstrap estimates obtained during analyses). Because both the PRODCLIN and bias-corrected bootstrapping confidence intervals do not contain zero, we reject the null hypothesis that $a_2 * b_2 = 0$ in the population and conclude that PANAS-PA is a significant mediator of the association between MAAS scores and WISDM scores, using Strategy 3 and 4.

Perceived Stress. Analyses revealed a robust effect of the MAAS on the PSS ($B = -1.50 [.24]$, $p < .001$). The path between PSS and the WISDM, while controlling for the MAAS, PANAS-

NA, the PANAS-PA, and the D-IAT, was not significant ($B = -0.80$ [.55], $p = .15$). We concluded that the PSS was not a significant mediator using the causal steps approach.

The Sobel test (Strategy 2), PRODCLIN (Strategy 3), and bias-corrected bootstrapping (Strategy 3) revealed similar results to Strategy 1. Using the Sobel test, multiplying the a_3 and b_3 path coefficients resulted in an indirect effect of $a_3*b_3 = 1.20$. Dividing a_3*b_3 by an estimate of the standard error of a_3*b_3 yielded a nonsignificant z-statistic ($z = 1.41$, $p = .16$). PRODCLIN yielded a point estimate of $a_3*b_3 = 1.20$ and 95% confidence intervals with a lower bound of $-.39$ and an upper bound of 2.95 . Bias-corrected bootstrapping resulted in a point estimate of $a_3*b_3 = 1.18$ bounded by a lower bound of -0.42 and an upper bound of 3.12 (95% CI $[-0.42, 3.12]$). Because both the PRODCLIN and bias-corrected bootstrapping confidence intervals contain zero, we do not reject the null hypothesis that $a_3*b_3 = 0$ in the population and conclude that PSS scores do not significantly mediate the association between MAAS scores and WISDM scores, using Strategy 3 and 4.

Decentered Perspective. Analyses revealed a robust effect of the MAAS on the D-IAT ($B = -0.14$ [0.04], $p < .001$). The path between the D-IAT and the WISDM, while controlling for the MAAS, PANAS-NA, the PANAS-PA, and the PSS, was significant ($B = 4.65$ [2.33], $p = .05$). We concluded that the D-IAT was a significant partial mediator using the causal steps approach.

While PRODCLIN (Strategy 3) and bias-corrected bootstrapping (Strategy 4) revealed a similar significant finding, the Sobel test (Strategy 2) was nonsignificant. Using the Sobel test, multiplying the a_4 and b_4 path coefficients resulted in an indirect effect of $a_4*b_4 = -0.65$. Dividing a_4*b_4 by an estimate of the standard error of a_4*b_4 yielded a nonsignificant z-statistic ($z = -1.71$,

$p = .08$). PRODCLIN yielded a point estimate of $a_4*b_4 = -.65$ and 95% confidence intervals with a lower bound of -1.49 and an upper bound of -0.28 (95% CI [-1.49, 0.28]). Bias-corrected bootstrapping resulted in a point estimate of $a_4*b_4 = -0.64$ bounded by a lower bound of -1.72 and an upper bound of -0.12 (95% CI [-1.72, -0.12]). Because both the PRODCLIN and bias-corrected bootstrapping confidence intervals do not contain zero, we reject the null hypothesis that $a_4*b_4 = 0$ in the population and conclude that D-IAT scores do significantly mediate the association between MAAS scores and WISDM scores, using Strategy 3 and 4. Because three out of four strategies found the D-IAT scores to be a significant partial mediator, the effect is likely to be real.

As stated above, a total effect of the MAAS on the WISDM was found ($c = -4.27$ [1.19], $p < .001$). After partialling out the variance in this association explained by the indirect effects of the four mediators under study, the direct effect of the MAAS on the WISDM was significant but reduced ($c' = -2.67$ [1.34], $p = .05$). The specific indirect effects identified ($a_1*b_1 = -.90$, $a_2*b_2 = -1.24$, $a_3*b_3 = 1.20$, $a_4*b_4 = -.65$) added to the direct effect ($c' = -2.67$) equals the total effect ($c = -4.27$). The model explains approximately 40% of the effect of the MAAS on the WISDM, indicating that other processes not represented in the current model account for the remaining 60% of the total effect.

Sensitivity Analysis: Multiple Mediator Model with Covariates To further test the hypothesized model, results were replicated using all four strategies while controlling for age and sex (see Table 7 and Figure 9). As stated earlier, age was found to be significantly correlated with scores on the MAAS, such that older individuals yielded higher scores on the

MAAS. Sex was correlated with WISDM scores such that female sex was associated with higher WISDM scores. A similar pattern of results was obtained while controlling for covariates with two exceptions. Using Strategy 1, the causal steps approach, the D-IAT no longer remained a significant mediator. Specifically, the b path (Step 3) just failed to reach significance ($B = 4.15$ [2.27], $p = .07$). Similarly, using Strategy 3, PRODCLIN, the D-IAT also did not remain significant. Analyses revealed a point estimate of $a_4 * b_4 = -0.54$ and 95% confidence intervals with a lower limit of -1.30 and an upper limit of 0.02. The D-IAT remained a significant mediator using Strategy 4, Bootstrapping, the most powerful method of testing mediation. The pattern of results described above supported both the conclusion that the D-IAT is a significant mediator and the importance of using more powerful tests of mediation.

Discussion

Several findings of interest emerged from the present study. As hypothesized, positive affect and a decentered perspective to depressive stimuli mediated the negative association between mindfulness and dependence. Contrary to hypotheses, negative affect and perceived stress were not mediators of the mindfulness-dependence relationship. Finally, the use of modern and powerful meditational analyses, such as bias-corrected bootstrapping, revealed that a decentered perspective was a significant mediator in the unadjusted model, whereas using traditional methods, such as the causal steps and the Sobel test, would have left this research question unanswered.

As hypothesized, positive affect partially mediated the association between mindfulness and dependence when controlling for negative affect, perceived stress, and a decentered perspective. Specifically, higher levels of dispositional mindfulness were associated with higher levels of positive affect. Increased positive affect in turn was associated with lower dependence on tobacco. Current clinical practice guidelines focus heavily on reducing craving and negative affect through nicotine replacement therapy, problem-solving, and cognitive-behavioral interventions. Developing and using interventions that improve positive affect, such as mindfulness-based interventions, will likely impact treatment pathways not affected by conventional treatments. Identifying and impacting additional treatment pathways is necessary in order to improve the 15% success rate of quit attempts.

While positive affect was a significant mediator of the negative association between dispositional mindfulness and cigarette-smoking dependence, it is likely not accurate to

conclude that mindfulness reduces to trait positive affect. The association between dispositional mindfulness and dependence remained significant while controlling for positive affect, suggesting that much of the variance in the association remains unexplained. Additionally, a small but growing body of literature documented associations between mindfulness meditation and improvements in cognitive functioning (attention, working memory, and executive function) (Chiesa, Calati, & Serretti, 2011). If mindfulness training reduced to trait positive affect, then improvements in cognition would be unexpected. Studying the effect of other methods of increasing positive affect on cigarette-smoking dependence and behavior may be warranted. Other methods of increasing positive affect include aerobic activity (Reed & Buck, 2009), using positive imagery (Holmes, Lang, & Shah, 2009; Sheldon & Lyubomirsky, 2006), and expressing gratitude (Seligman, Park, & Peterson, 2005; Sheldon & Lyubomirsky, 2006).

A decentered perspective to depression-related stimuli partially mediated the association between mindfulness and cigarette dependence while controlling for negative affect, positive affect, and perceived stress. Like positive affect, this finding suggests an additional pathway that may be used to make future smoking cessation interventions more successful. However, a better understanding of the role of a decentered perspective is needed before this variable can be successfully operationalized.

Currently, a consensus has not yet been reached as to whether the decentered perspective construct applies to all contents of consciousness or a specific subset. Shapiro et al. (2006) described *reperceiving*, a similar construct, as “a fundamental shift in perspective”

through which “one is able to disidentify from the contents of consciousness (i.e. one’s thoughts) and view his or her moment-by-moment experience with greater clarity and objectivity (Shapiro et al., 2006, p. 5).” Brach (2012) used the acronym RAIN to describe a brief mindfulness intervention similar to the decentered perspective and intended for use with “intense and difficult emotions.” RAIN stands for “Recognize what is happening; Allow life to be just as it is; Investigate inner experience with kindness; and Non-identification (Brach, 2012).” Teasdale (2004) described mindfulness as an alternate cognitive mode that is “an exact antithesis to the ruminative cognitive mode” found in depressed individuals (Teasdale, 2004, p. 276). As briefly discussed previously, Waters et al. (2009) found that a decentered perspective to depression-, but not smoking- or anxiety- related stimuli was positively associated with dispositional mindfulness scores in smokers. This finding suggests that the decentered perspective is specific to depression-related stimuli, rather than broadly applying to the contents of consciousness (Waters et al., 2009). The finding also supported Teasdale’s description of a decentered perspective as a cognitive mode that provides special protection from rumination.

The decentered perspective warrants future study including experimentally manipulating mindfulness and measuring the effect on a decentered perspective to depressive stimuli and tobacco-smoking dependence. Additional research is needed to validate the D-IAT as a measure of a decentered perspective and to develop additional validated measures of a decentered perspective. Currently, there is a single validated measure of a decentered perspective, a subscale of the Experiences Questionnaire (Fresco et al., 2007).

Contrary to hypotheses, negative affect and perceived stress were not significant partial mediators of the association between mindfulness and cigarette dependence. This finding is especially surprising considering the well-documented negative associations between negative affect, stress, and mindfulness and the equally well-documented positive associations between negative affect, stress, and tobacco dependence. Several authors have suggested that mindfulness may moderate the association between negative affective states and substance use. Individuals high in mindfulness may be able to tolerate negative affective states without relapsing, whereas individuals low in mindfulness may experience the same negative affective states without being able to maintain abstinence. Specifically, Bowen and Marlatt (2009) found that mindfulness training significantly moderated the relationship between negative affect and urges to smoke such that participants in the mindfulness group displayed a weaker relationship between affect and urges to smoke than participants in the control group. Gifford et al. (2004) found that absolute levels of negative affect and withdrawal symptoms did not predict quit rates, while having an avoidant or inflexible response style to negative affective states did predict quit rates in their study of ACT for smoking cessation. This finding provides more evidence that mindfulness training may reduce smoking by changing an individual's response to negative affect instead of changing the level of negative affect experienced. A future study that experimentally manipulates mindfulness and uses EMA methodology to measure state negative affect and relapses during a quit attempt would be useful in further testing this hypothesis.

Having a decentered perspective was a significant mediator using the causal steps, PRODCLIN, and bias-corrected bootstrapping; however, the Sobel test was not significant. The

causal steps and the Sobel test are older, more widely used, and less powerful than PRODCLIN and bias-corrected bootstrapping. Had the analyses been limited to the more traditional tests, the causal steps would have revealed a significant partial mediator and the Sobel test would have revealed a non-significant effect. Limited to the two tests, the conservative investigator would be unable to conclude that a decentered perspective is a significant partial mediator. Examining the results of PRODCLIN and bias-corrected bootstrapping in addition to the more traditional methods allows the conservative investigator to conclude with more confidence that the effect identified with the causal steps and verified with PRODCLIN and bias-corrected bootstrapping reflects a true effect in the population rather than a type I error. When controlling for age and sex, the results were more mixed. Partial mediation assessed with the bias-corrected bootstrapping, generally the most powerful method, retained significance, but the causal steps and PRODCLIN methods just failed to reach significance. It is likely that the effect is real; however, only bias-corrected bootstrapping had the power to correctly identify it in the current sample. These analyses will be repeated with a larger sample when data from the Project Mind main study is available.

Strengths

The current study had several notable strengths including the assessment of conceptually distinct mediators, the power of the study, the attempt to measure a decentered perspective, and the use of several statistical analyses to assess mediation. This study examined conceptually distinct mediators including affective processes (positive and negative affect), explicit cognitive processes (perceived stress), and implicit cognitive processes (a decentered

perspective). Previous studies of mindfulness for smoking cessation include one study that identified a single mediator. Gifford et al. (2004) operationalized and tested avoidance and inflexibility as a mediator of the association between mindfulness training and abstinence at follow-up. Despite being marginally underpowered, the data provided a large enough sample size to identify small to medium indirect effects. Finally, four different methods of assessing mediation were used. Methods included traditional methods (causal steps and the Sobel test) and newer, more powerful methods (PRODCLIN and bias-corrected bootstrapping). Replicating analyses with the different methods elucidated the utility of the more statistically advanced methods.

Limitations

Use of a cross-sectional design for testing mediation was the main limitation of the study. Using cross-sectional data to study what is by definition a longitudinal process often results in biased - potentially greatly biased - estimates of longitudinal mediation parameters (Maxwell & Cole, 2007). If a significant indirect effect in a cross-sectional study were observed, then the finding would not necessarily mean that a significant indirect effect would be present in a longitudinal dataset. Similarly, if a non-significant indirect effect in a cross-sectional study were observed, then it is still possible that a significant indirect effect would be present longitudinally. In light of this limitation, the current study is hypothesis generating.

A second limitation is that we did not manipulate mindfulness as an experimental variable. Therefore, the pattern of causal relationships remains uncertain. The dependent variable was dependence on cigarettes rather than abstinence during a quit attempt. Measures

of dependence are strongly related to variables of interest such as abstinence, withdrawal, and biomarkers for metabolism of nicotine (Piper, et al., 2007). However, it is possible that a mediating role of negative affect and perceived stress would have been revealed if abstinence were the dependent variable.

Finally, the depression IAT is a novel and currently unvalidated measure of a decentered perspective. While using the depression IAT may introduce bias by assuming that mindfulness is a positive state of mind, there is both theoretical and empirical evidence suggesting that mindfulness is positively associated with positive affect and is incompatible with depressive rumination (Brown & Ryan, 2003; Teasdale, 2004; Waters, et al., 2009).

Future Directions

Future directions for research include using the Project Mind main study data to replicate and extend the present findings. The main study consists of an RCT of Mindfulness-Based Therapy for Smoking versus Health Education and Cognitive Behavioral Therapy. The new study provides several improvements over the current study. The main study used an eight week Mindfulness Based Therapy for Smoking intervention to experimentally manipulate mindfulness. During the fifth week of training, participants attempted to quit smoking. Participants were followed for 26 weeks post-quit. This design allows for stronger conclusions about causality to be drawn based on the chronological measurement of the variables. The independent variable, treatment condition, was manipulated prior to quit day. Mediators were measured at the quit day (Week 0) and the dependent variable, abstinence, was measured at Week +26. Additionally, using abstinence as the dependent variable (instead of dependence)

allows for the study of the behavioral variable of interest (abstinence), instead of a psychological proxy (dependence).

Additionally, a future study was planned using ecological momentary assessment (EMA) methodology to test the efficacy of a brief mindfulness intervention for smoking reduction. The study will provide two weeks of longitudinal data. Mindfulness will be manipulated by administering a twenty-minute mindfulness intervention on a hand-held device once per day. Two measures of mindfulness, the MAAS and the Toronto Mindfulness Scale (Lau et al., 2006), will be used to triangulate on this key construct. Additionally, two measures of a decentered perspective will be used, the depression IAT and the Experiences Questionnaire (Fresco, et al., 2007), a validated self-report measure. Smoking rate, dependence, and salivary cotinine will be measured. The second study will provide an opportunity to replicate the current study's findings. Additionally, using EMA methodology would allow for more fine-grained analysis of variables (mindfulness, cognition, emotion, and smoking) that likely share associations of reciprocal causality. For example, whether a brief mindfulness intervention influences affect and implicit cognition can be examined, and whether the association between affect and craving/smoking is attenuated in the mindful group can be assessed. Using a brief mindfulness intervention will also provide information about the dose-response curve of mindfulness for smoking. Finally, it may be useful in future research to include measures of attention and executive function, as a recent meta-analysis has revealed that mindfulness can improve these cognitive functions (Chiesa et al., 2011).

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Footnotes

¹Power analyses for the Sobel test were computed using R 2.11.1 and a simulation (Yuan, n.d.). The simulation provides power for the Sobel test using inputted values for the a path, b path, c' path, and sample size. 1000 repetitions were used for each simulation. Using a sample size of 140, there was 96% - 100% power to detect a significant mediation effect when both the a and b path were greater than or equal to beta (standardized regression coefficient) = 0.39, a medium effect. Reducing either the a path or the b path below beta = 0.39 to beta = 0.26 (a small-to-medium effect), requires an increase in the other path to beta = 0.59, a large effect, in order to maintain 82 - 84% power to detect a significant mediation effect. Power was not degraded by varying the c' path from beta = 0 (complete mediation) to beta = 1 for the combinations of a and b paths described above. Power analyses were not conducted for the other three tests of mediation because simulation software for these tests was not readily available.

Table 1

Summary of the Mindfulness Intervention for the Cigarette-Smoking Cessation Literature

Study	Purpose of Study	Participants	Intervention	Independent Variables	Dependent Variables	Main Findings
Altner (2002)	controlled non-randomized longitudinal study of MBSR for smoking in a workplace	117 hospital employees	MBSR (8 week) course	Group (NRT, NRT + MBSR), time	Abstinence rates at 12 months	Abstinence: Lower abstinence rates at 12 months in the MBSR + NRT group: NRT = 24.6%; NRT + MBSR = 32.6%
Bowen and Marlatt (2009)	RCT of a brief mindfulness-based intervention (urge-surfing) on smoking behavior	123 (33 F, 90 M) nicotine deprived undergraduate students	Urge-surfing during cue exposure exercise (4 x 5 min)	Group (Urge-surfing, control), time	smoking rate at 7 day follow up	Cigarettes smoked per day for 7 days Significantly lower rates in the urge-surfing group (vs. control) Negative Affect No significant group x time interaction. Urges No significant group x time interaction. Moderation Analysis Mindfulness moderated the relation between negative affect and urge.

Brewer et al. (2011)	RCT of 4 week Mindfulness Treatment for smoking	87 (33 F, 54 M) treatment seeking smokers from the community	4 week course, two 1.5 hour sessions per week; 30 minute home practice	Group (MT, FFS), time	Smoking rate, Abstinence	<p>Smoking rate: MT group demonstrated greater reductions in cigarette use than control.</p> <p>Abstinence: MT group displayed trend towards greater abstinence immediately following treatment. Trend was significantly different at the 17 week follow-up. Point prevalence abstinence for MT was 30% vs. 5% in control.</p> <p>Home Practice: Home practice correlated with less cigarette use at the end of treatment.</p>
Cropley, Ussher, and Charitou (2007)	RCT of a brief mindfulness-based intervention (body scan) on desire to smoke	30 (12 F, 18 M) overnight abstinent smokers from the community	body scan (10 minute)	group (body scan, control); time (5, 10, 15 minutes)	strength of desire to smoke; irritability, restlessness, and tension	<p>Strength of desire to smoke: Significant group by time interaction.</p> <p>Irritability: Main effect of group. Main effect of time.</p> <p>Restlessness: Main effect of group. Main effect of time.</p> <p>Tension: Main effect of group. Main effect of time.</p>
Davis, Fleming, Bonus, and Baker (2007)	uncontrolled nonrandomized pilot study of MBSR for smoking cessation	18 (10 F, 8 M) community sample	MBSR (8 week) course	Meditation compliance, smoking, stress, affective distress,	Smoking abstinence	<p>Abstinence: 55% point-prevalence abstinence at 6 week follow up</p>

Gifford et al. (2004)	RCT of ACT vs. NRT for smoking cessation	76 (59% F, 41% M) community sample of smokers	ACT (seven week) (weekly individual and group therapy)	Group (ACT vs. NRT), Time	24 hour point prevalence smoking	Abstinence: ACT (vs. Control) significantly better abstinence rates at one year (Wald χ^2 (1, N = 55) = 4.07, p = .04). No difference at post, and six-month follow-up.
Leigh, Bowen, and Marlatt (2005)	cross-sectional study of mindfulness, spirituality, alcohol, and tobacco use	196 (123 F, 70 M, 3 UNK) undergraduate students	N/A	smoking status (smoker, non-smoker) drinking status (frequent binge, non-drinker)	Mindfulness (FMI), Spirituality	Mindfulness: Smokers (vs. non-smokers) have significantly higher level of mindfulness. Frequent Binge Drinkers (vs. non-drinkers) have significantly higher levels of mindfulness.
Rogojanski, Vetesse, and Antony (2011)	RCT of urge-surfing vs. suppression	61 (25 F, 36 M)	Urge-surfing during cue exposure	Condition (mindfulness vs. suppression); time	Smoking, self-efficacy, craving, nicotine dependence, affect, and depression	Smoking amount: Main effect of time. No significant differences between study conditions. Self-efficacy: Main effect of time. No significant differences between study conditions. Craving: No significant differences. Negative Affect: Significantly reduced in the mindfulness condition. Depression: Significantly reduced in the mindfulness condition. Nicotine Dependence: Significantly reduced in the mindfulness condition.

Ussher, Cropley, Playle, Mohidin, and West (2009)	RCT of body scan and isometric exercise vs. control	48 (17 F, 31 M) smokers from the community	Ten minute body scan in the lab; followed by another ten minute body scan in the natural environment within three hours	Group (body scan (BS), isometric exercise (IE), control); Time (pre, post, 5 minute, ten minute); Location (lab, natural environment)	strength of desire to smoke; irritability, restlessness, tension, difficulty concentrating, stress	<p>Overall: No significant differences noted between BS and IE in the lab or the natural environment.</p> <p>Strength of desire to smoke: Significantly lower scores in BS and IE (vs. control) in lab and natural environment.</p> <p>Irritability: Significantly lower scores in BS and IE (vs. control) in lab. Significantly lower scores in BS (vs. control and marginally significantly lower scores in IE (vs. control) in the natural environment.</p> <p>Restlessness: Significantly lower scores in BS and IE (vs. control) in natural environment (but not lab).</p> <p>Tension: No significant differences in lab; marginally lower scores in BS (vs. control) and significantly lower scores in IE (vs. control) in natural environment.</p> <p>Difficulty Concentrating: Significantly lower scores in BS and IE (vs. control) in lab and natural environment.</p> <p>Stress: Significantly lower scores in BS and IE (vs. control) in lab (but not natural environment).</p>
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Vidrine et al. (2009)	Cross-sectional study of dispositional mindfulness, nicotine dependence, withdrawal, and agency	158 (45% F, 55% M)	N/A	Mindfulness (MAAS)	Nicotine Dependence, withdrawal, and agency	Mindfulness: negatively associated with nicotine dependence and withdrawal and positively associated with agency.
Waters et al. (2009)	Cross-sectional study of dispositional mindfulness, affect, attention, and decentered perspective	158 (45% F, 55% M)	N/A	Mindfulness (MAAS)	Positive Affect, Negative Affect, Perceived Stress, CESD, Smoking IAT, Anxiety IAT, Depression IAT, Smoking Stroop, Anxiety Stroop, Depression Stroop	Mindfulness positively associated with positive affect and negatively associated with negative affect, perceived stress, D-IAT, and CESD. Nonsignificant finding for smoking stroop, anxiety stroop, depression stroop, smoking IAT, and anxiety IAT.

Table 1 Note: ACT = Acceptance and commitment therapy; CESD = Center for epidemiological studies depression scale; F = female; FMI = Freiburg Mindfulness Inventory; D-IAT = Depression Implicit Association Test; M = male; MBSR = Mindfulness-based stress reduction; NRT = Nicotine replacement therapy; RCT = Randomized controlled trial; SE= Standard error; UNK = unknown.

Table 2

Demographic Statistics

	Overall	Caucasian	African-American	Other
Race		58.6%	32.1%	9.3%
Gender				
Male	55%	56.1%	46.7%	69.2%
Female	45%	43.9%	53.3%	30.8%
Hispanic	11.4%	14.6%	2.2%	23.1%
Education (M [SD])	13.49 (2.45)	13.82 (2.38)	12.80 (2.41)	13.77 (2.71)
Age (M [SD])	43.76 (11.78)	44.89 (11.68)	43.33 (11.98)	38.08 (10.76)
Marital Status				
Married/Cohabiting	37.2%	43.9%	28.9%	23.1%
Single	32.1%	24.4%	44.4%	38.5%
Divorced	22.1%	24.4%	15.6%	30.8%
Other	8.6%	7.4%	11.1%	7.7%
Employed	57.9%	62.2%	51.0%	53.8%
Income < \$20,000	31.4%	23.2%	44.4%	38.5%
Cigarettes per day (M [SD])	20.40 (9.25)	22.34 (9.14)	17.89 (7.57)	16.85 (12.38)
Years smoked (M [SD])	25.00 (12.07)	27.18 (12.34)	22.78 (11.49)	18.92 (9.23)

Table 2 Note: M = mean; SD = Standard Deviation.

Table 3

Depression Implicit Association Test

Block	No. Trials	Items assigned to LEFT key response	Items assigned to RIGHT key response
1	24	DEPRESSED	NOT DEPRESSED
2	24	me	not me
3	24	DEPRESSED + me	NOT DEPRESSED + not me
4	48	DEPRESSED + me	NOT DEPRESSED + not me
5	48	NOT DEPRESSED	DEPRESSED
6	48	NOT DEPRESSED + me	DEPRESSED + not me
7	48	NOT DEPRESSED + me	DEPRESSED + not me

Table 3 note. This description of the D-IAT is taken from previous studies that have utilized the IAT in smoking cessation research (e.g., Waters et al., 2007 and Waters et al., 2009). Blocks in bold denote critical trial blocks (Tasks 1 and 2). The IAT consisted of seven blocks: (1) Practice of single categorization for the first concept (e.g., DEPRESSED / NOT DEPRESSED); (2) Practice of single categorization for the second concept (e.g., me / not me); (3) First block of the combined categorization task (Task 1) (e.g., DEPRESSED + me / NOT DEPRESSED + not me); (4) Second block of the combined categorization task (Task 1); (5) Practice of single categorization for the target concept but with the response keys reversed from the block 1 assignment (e.g., NOT DEPRESSED / DEPRESSED); (6) First block of Task 2 (e.g. NOT DEPRESSED + me / DEPRESSED + not me); (7) Second block of Task 2. The order of completion of the combined categorization blocks (i.e., 3, 4, and 6, 7) was counterbalanced across participants.

Table 4

Descriptive Statistics

Variable	Min	Max	Mean	SD
MAAS	1.87	6.00	4.12	0.97
PANAS-NA	10.00	50.00	20.84	8.64
PANAS-PA	13.00	49.00	32.51	8.86
PSS	0.00	15.00	6.54	3.14
D-IAT	-1.64	0.78	-0.56	0.50
WISDM	19.21	90.71	56.41	14.55

Table 4 Note: D-IAT = Depression- Implicit association test; MAAS = Mindful attention and awareness scale; Max = Maximum; Min = Minimum; PANAS-NA = Positive and negative affect schedule – negative affect; PANAS-PA = Positive and negative affect schedules- positive affect; PSS = Perceived stress scale; SD = Standard Deviation; WISDM = Wisconsin inventory of smoking dependence motives.

Table 5

Depression Implicit Association Test (D-IAT) Completers vs. Non-completers Comparison of Demographic Statistics

	Completers	Non-Completers	χ^2	p-value
Race			3.36	.64
Caucasian	58.6%	50%		
African-American	32.1%	50%		
Other	9.3%	0%		
Ethnicity			2.29	.13
Hispanic	11.4%	0%		
Non-Hispanic	88.6%	100%		
Gender			0.30	.58
Male	55%	61.1%		
Female	45%	38.9%		
Marital Status			3.49	.63
Married/Cohabiting	37.2%	44.4%		
Single	32.1%	27.0%		
Divorced	22.1%	16.7%		
Other	8.6%	11.1%		
Employed	57.9%	50%	0.40	.53
Income < \$20,000	31.4%	44.4%	0.95	.33
			t (156) =	p - value
Education (M [SD])	13.49 (2.45)	13.00 (2.77)	-0.78	.44
Age (M [SD])	43.76 (11.78)	44.39 (11.90)	0.21	.83
Cigarettes per day (M [SD])	20.40 (9.25)	23.50 (8.83)	1.35	.18
Years smoked (M [SD])	25.00 (12.07)	23.33 (12.61)	-0.55	.58

Table 5 Note: M = mean; SD = Standard Deviation.

Table 6

Depression Implicit Association Test (D-IAT) Completers vs. Non-completers Comparison of Independent Variable, Mediators, and Dependent Variable

Variable	D - IAT Completers M (SD) ^a	D-IAT Non-Completers M (SD) ^b	t (156) =	p - value
MAAS	4.12 (.97)	4.39 (.94)	1.10	.28
PANAS-NA	20.84 (8.64)	20.94 (10.40)	0.05	.96
PANAS-PA	32.51 (8.86)	31.67 (10.13)	-0.37	.71
PSS	6.54 (3.14)	6.67 (2.74)	0.17	.87
WISDM	56.32 (14.23)	57.10 (17.31)	0.20	.84

Table 6 Note: D-IAT = Depression- Implicit association test; MAAS = Mindful attention and awareness scale; M = Mean; PANAS-NA = Positive and negative affect schedule – negative affect; PANAS-PA = Positive and negative affect schedules- positive affect; PSS = Perceived stress scale; SD = Standard Deviation; WISDM = Wisconsin inventory of smoking dependence motives. ^an = 140, ^bn = 18.

Table 7

Summary of Results

Mediator	Cov	BK c (SE)	BK a (SE)	BK b (SE)	BK c' (SE)	Sobel a*b (z)	PRODCLIN a*b [LL, UL]	Bootstrapping a*b [LL, UL]
PANAS-NA		-4.27 (1.19)***	-3.90 (.68)**	0.23 (.17)	-2.67 (1.34)*	-0.90 (-1.30)	-0.90 [-2.31, .38]	-0.88 [-2.32, 0.58]
PANAS-PA		-4.27 (1.19)***	2.50 (.75)**	-0.50 (.15)**	-2.67 (1.34)*	-1.24 (-2.32)**	-1.25 [-2.43, -.37]	-1.23 [-2.83, -0.39]
PSS		-4.27 (1.19)***	-1.50 (.24)**	-0.80 (.55)	-2.67 (1.34)*	1.20 (1.41)	1.20 [-.39, 2.95]	1.18 [-0.42, 3.12]
D-IAT		-4.27(1.19)***	-0.14 (.04)***	4.65 (2.33)*	-2.67 (1.34)*	-0.65 (-1.71)	-.65 [-1.49, -0.28]	-0.64 [-1.72, -0.12]
PANAS-NA	+ Cov	-4.98 (1.19)***	-3.57 (.70)***	0.25 (.17)	-3.09 (1.31)*	-0.89 (-1.41)	-0.89 [-2.23, 0.27]	-0.89 [-2.26, 0.38]
PANAS-PA	+ Cov	-4.98 (1.19)***	2.83 (.77)***	-0.45 (.15)**	-3.09 (1.31)*	-1.27 (-2.32)*	-1.27 [-2.49, -0.36]	-1.29 [-2.92, -0.36]
PSS	+ Cov	-4.98 (1.19)***	-1.40 (.25)***	-0.59 (.54)	-3.09 (1.31)*	0.83 (1.07)	0.83 [-0.63, 2.42]	0.83 [-0.69, 2.65]
D-IAT	+ Cov	-4.98 (1.19)***	-0.13 (.04)**	4.15 (2.27)	-3.09 (1.31)*	-0.54 (-1.59)	-0.54 [-1.30, 0.02]	-0.55 [-1.57, -0.02]

Table 7 Note: Significant paths are bolded. c = path coefficient between the MAAS and WISDM; a = path coefficient between the MAAS and the mediators; b = path coefficient between the mediators and the WISDM; c' = direct path; a*b = the indirect effect; BK = Baron & Kenny Causal Steps Approach; Cov = Covariates (age and sex); D-IAT = Depression- Implicit Association Test; LL = Lower limit; PANAS-NA = Positive and negative affect schedule – negative affect; PANAS-PA = Positive and negative affect schedules- positive affect; PSS = Perceived stress scale; SE = Standard error; UL = Upper limit; z = z-score. *p < .05; **p < .01; ***p < .001

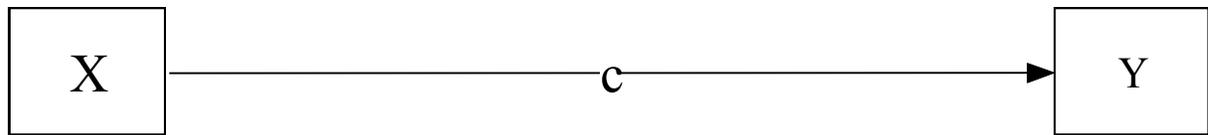
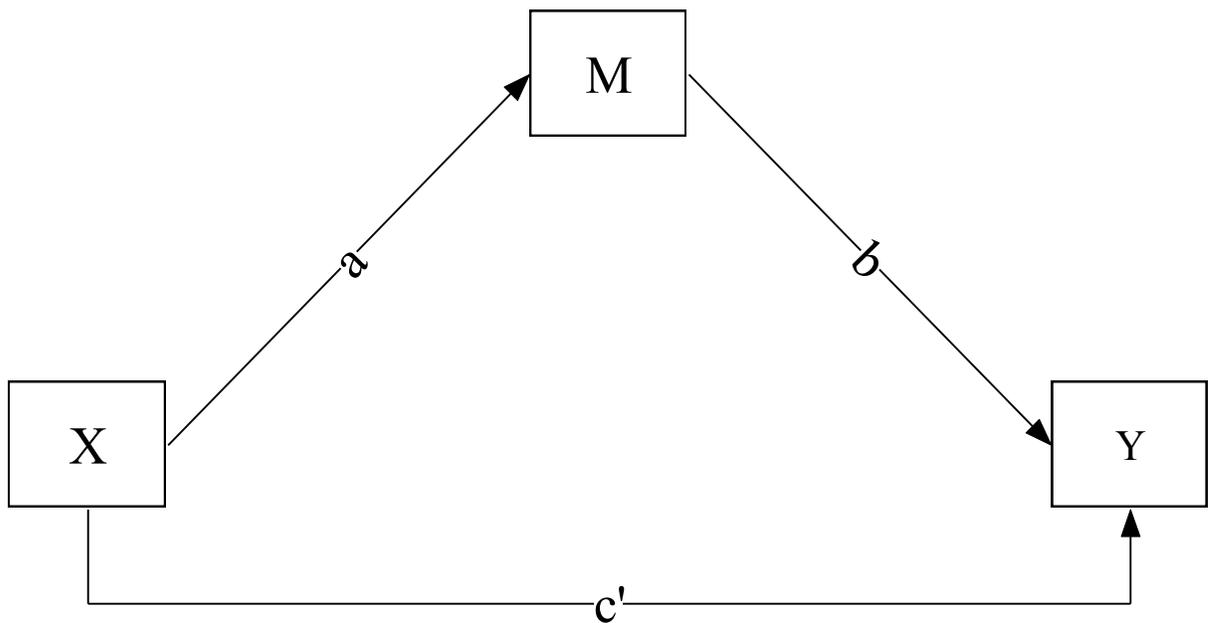
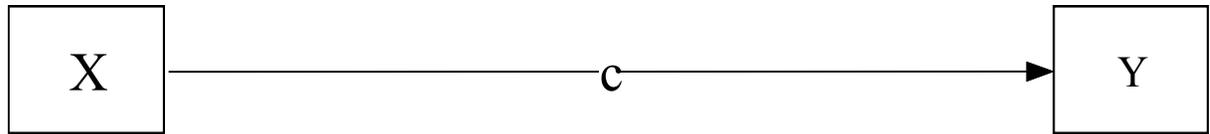
A**B**

Figure 1. Simple Mediation Path Model. Path diagram for (a) the total effect of the independent variable on the dependent variable, and (b) the indirect effect ($a*b$) of the independent variable on the dependent variable through the mediator variable. c' is the direct (unmediated) path from X to Y. Adapted from Fritz & MacKinnon (2007).

A



B

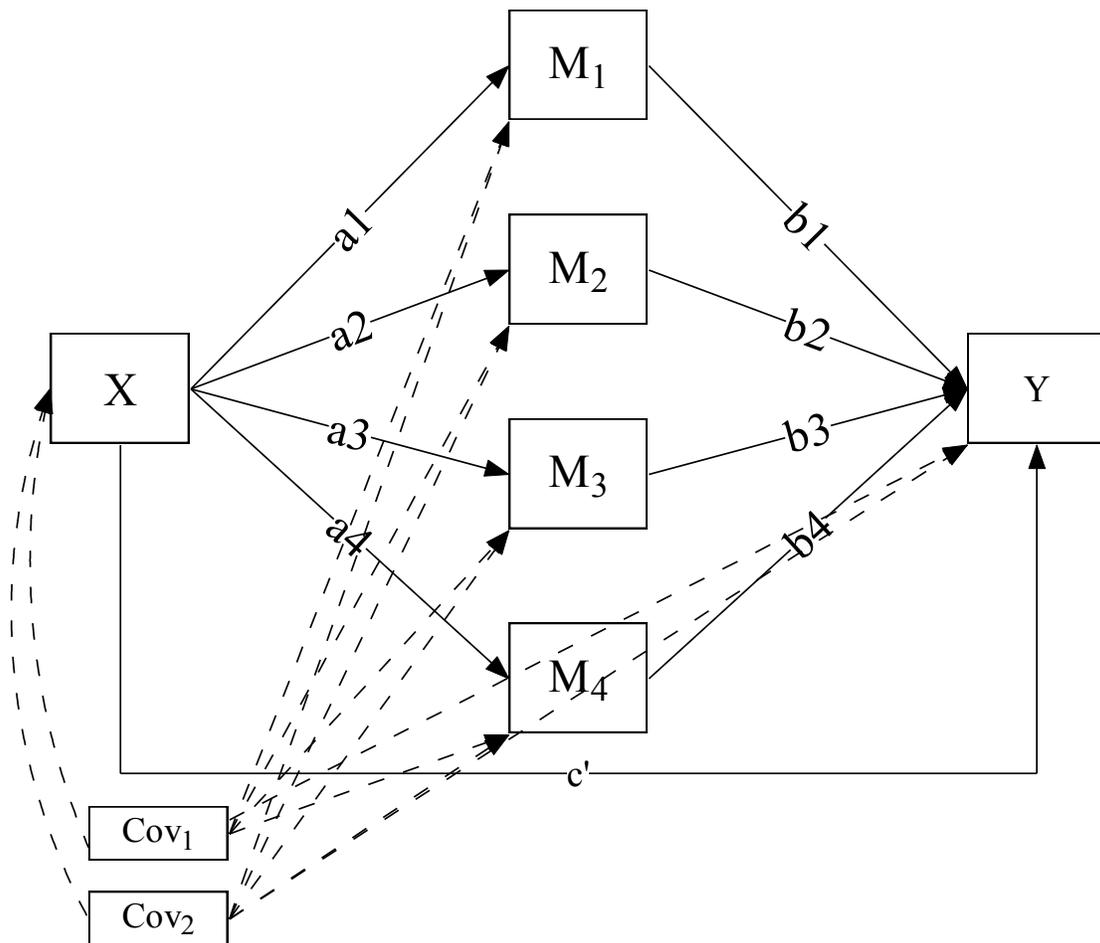


Figure 2. Multiple Mediation Path Model. Path diagram for the specific indirect effects of the independent variable on the dependent variable through four mediator variables while controlling for covariates. Adapted from A.F. Hayes (n.d.).

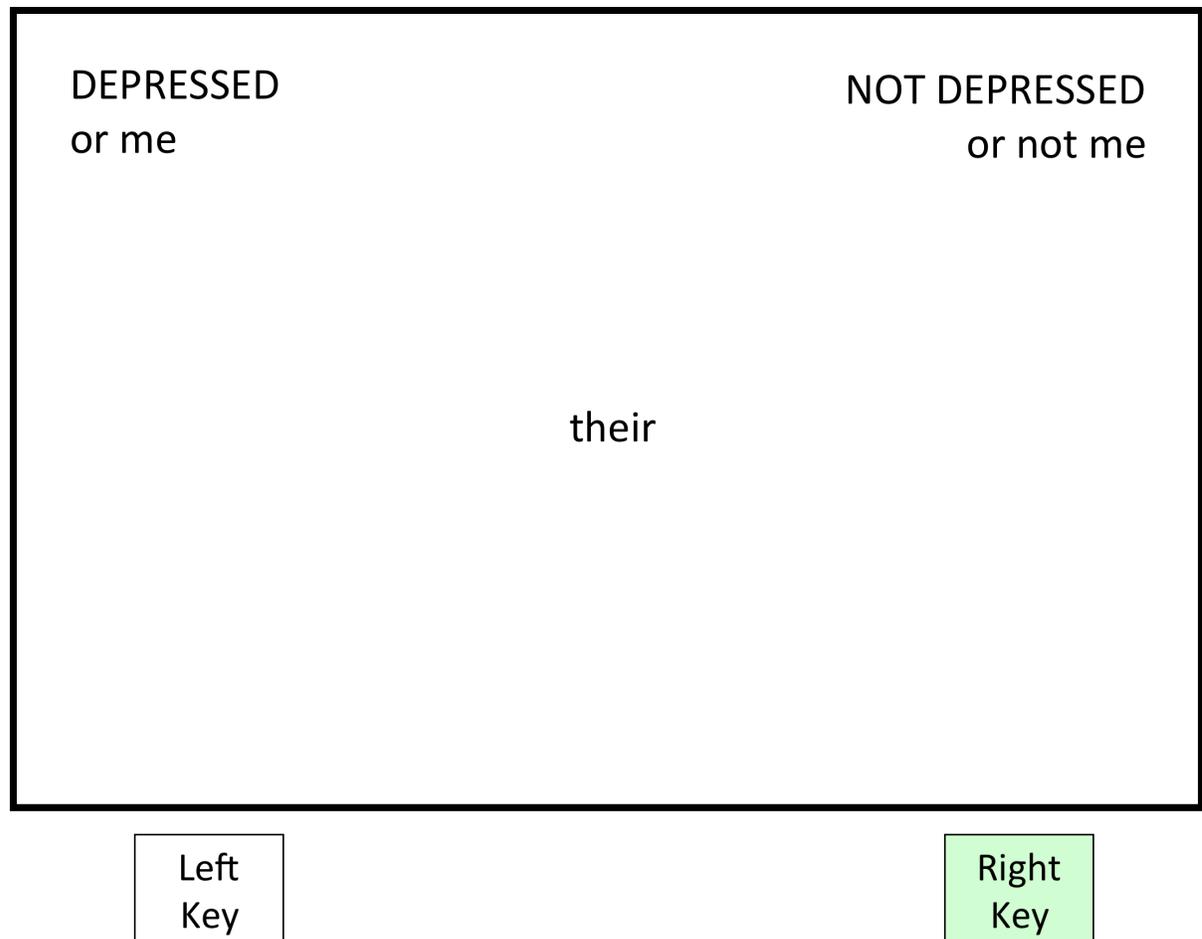


Figure 3. Representation of the Depression Implicit Association Test (D-IAT): Task 1.

Category labels appear on the upper left and upper right of the screen. The stimulus words to be categorized appear in the center of the screen. A participant would respond with a right key press because the stimulus word is in the “not me” category.

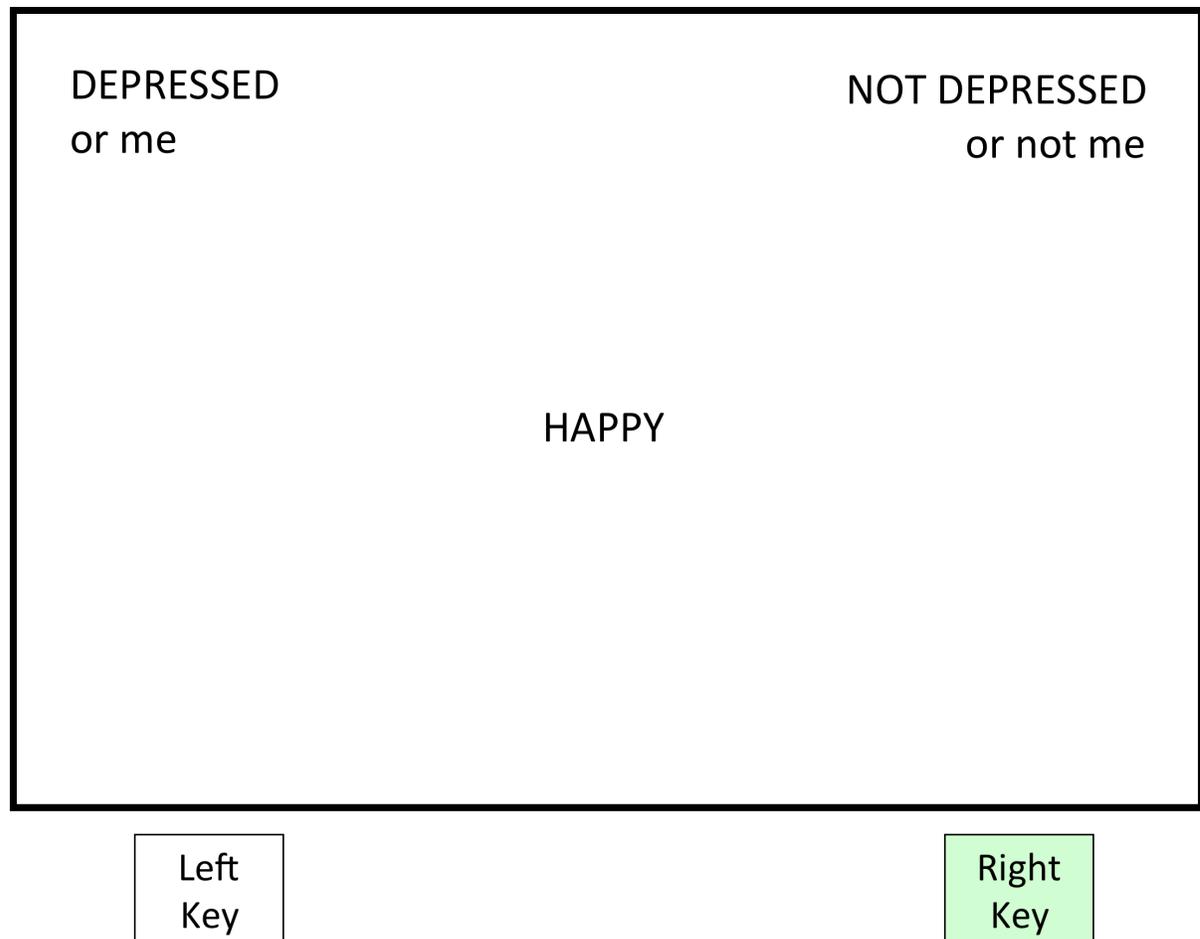


Figure 4. Representation of the Depression Implicit Association Test (D-IAT): Task 2. In Task 2, the category labels “me” and “not me” are switched, changing the sorting task. Category labels appear at the top of the screen and the stimulus word appears in the center of the screen. A participant would respond with a right key press because “Happy” falls into the “NOT DEPRESSED” category of words.

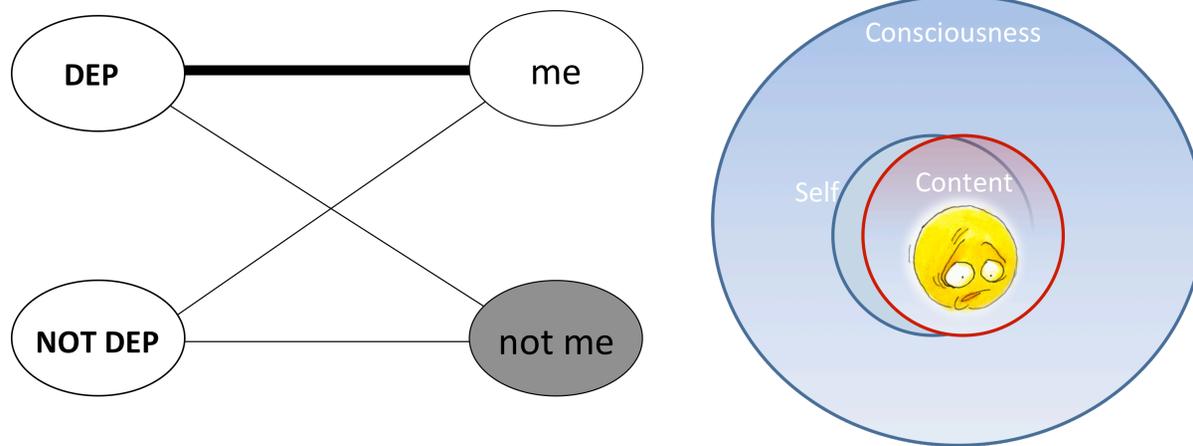


Figure 5. Conceptual depiction of a positive D-score on the Depression Implicit Association Test (D-IAT) and the accompanying lack of a decentered perspective. A high (more positive) D-score represents a strong mental association between “DEPRESSION” and “me” (left). This pattern of results corresponds with a lack of a decentered perspective (right) resulting in an individual who does not effectively separate negative contents of consciousness from their sense of self.

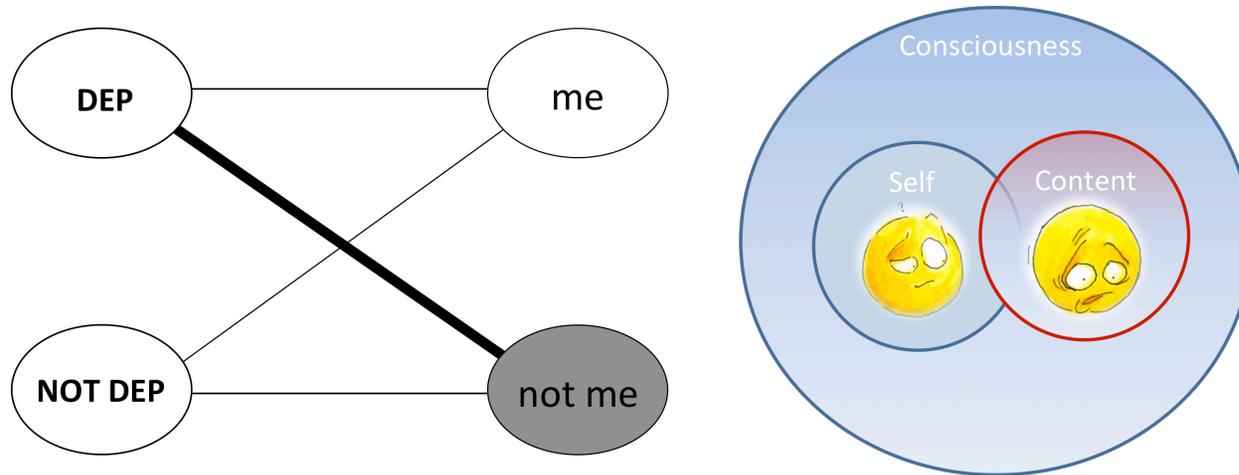


Figure 6. Conceptual depiction of a negative D-score on the Depression Implicit Association Test (D-IAT) and the accompanying decentered perspective. A low (more negative) D-score represents a strong mental association between “DEPRESSION” and “not me” (left). This pattern of results corresponds with a decentered perspective (right) resulting in an individual who effectively separates negative contents of consciousness from their sense of self.

MINDFULNESS AND SMOKING DEPENDENCE: MECHANISMS

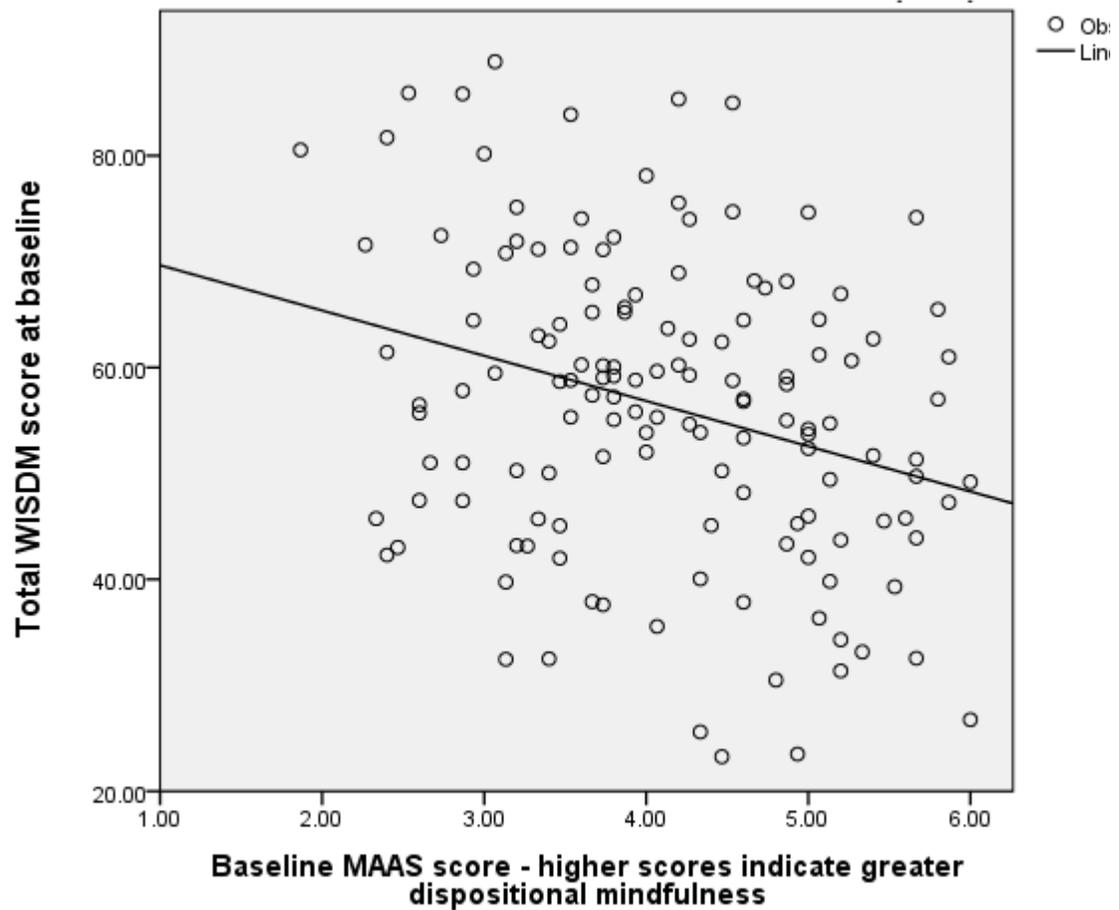


Figure 7. Negative association between mindfulness and dependence. A one unit change in the MAAS (approximately one standard deviation) results in a -4.27 unit change in predicted scores on the WISDM (approximately one third of a standard deviation) in predicted scores on the WISDM ($t = -4.27, SE = 1.19$). MAAS = Mindful attention and awareness scale; WISDM = Wisconsin inventory of smoking dependence motives.

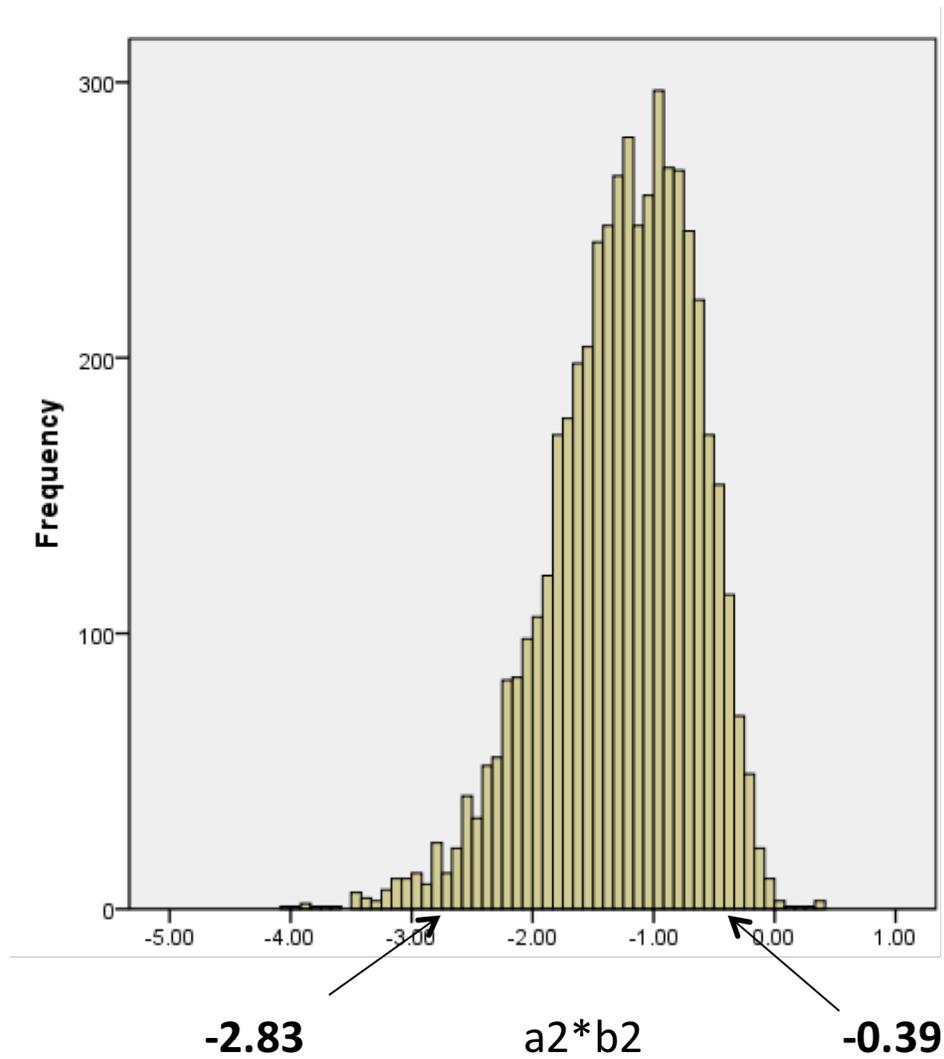


Figure 8. Distribution of 5000 bootstrap estimates of the specific indirect effect of mindfulness on dependence through positive affect. $a * b = -1.23$; lower limit = -2.83; upper limit = -0.39.

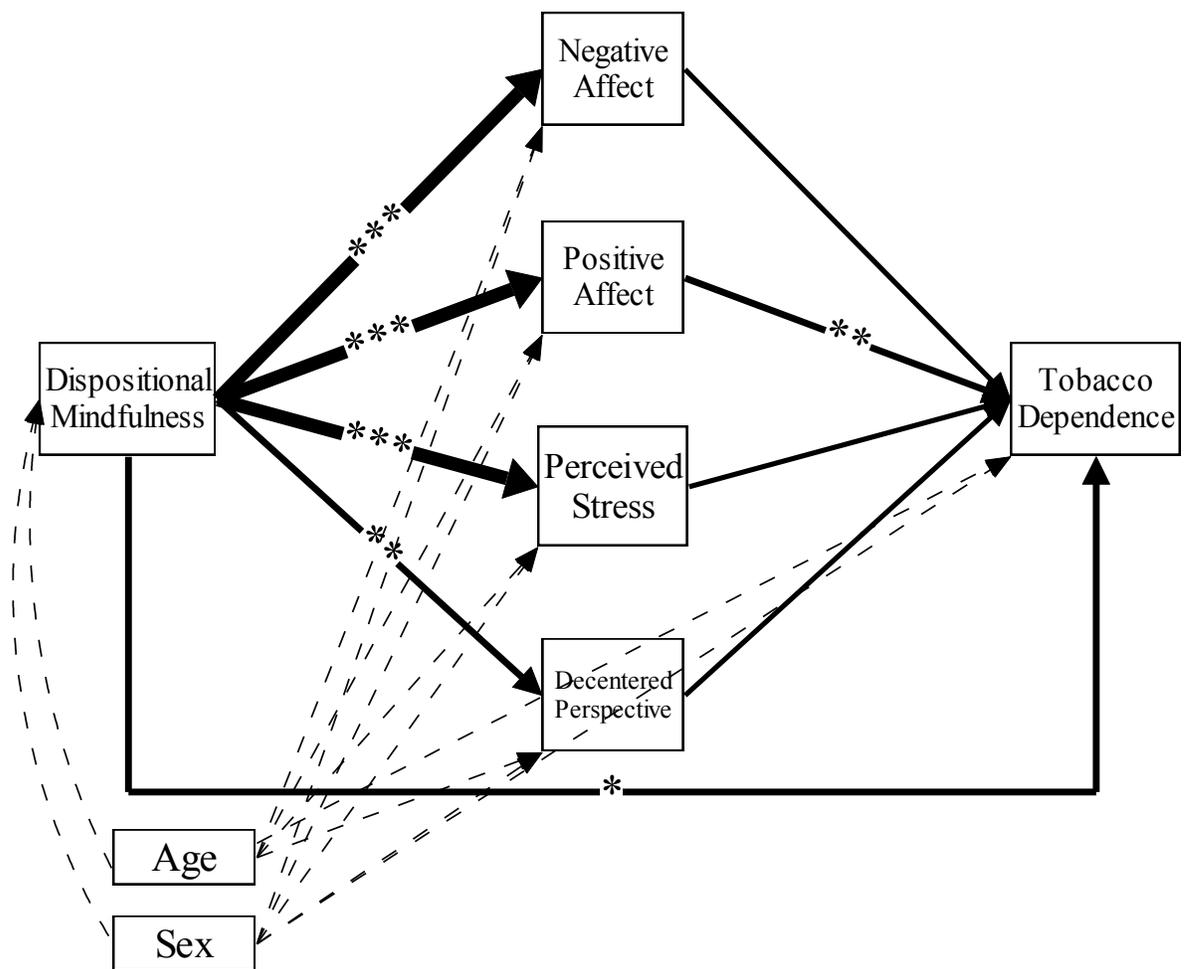


Figure 9. Results from analyses using the Causal Steps method and a multiple mediator model while controlling for covariates (age and sex). Significant paths appear in bold. * $p < .05$, ** $p < .01$, *** $p < .001$.

APPENDIX A Self Report Measures

Mindful Attention and Awareness Scale

Day-to-Day Experiences

Instructions: Below is a collection of statements about your everyday experience. Using the 1-6 scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what *really reflects* your experience rather than what you think your experience should be. Please treat each item separately from every other item.

1	2	3	4	5	6
Almost Always	Very Frequently	Somewhat Frequently	Somewhat Infrequently	Very Infrequently	Almost Never

I could be experiencing some emotion and not be conscious of it until some time later.	1	2	3	4	5	6
I break or spill things because of carelessness, not paying attention, or thinking of something else.	1	2	3	4	5	6
I find it difficult to stay focused on what's happening in the present.	1	2	3	4	5	6
I tend to walk quickly to get where I'm going without paying attention to what I experience along the way.	1	2	3	4	5	6
I tend not to notice feelings of physical tension or discomfort until they really grab my attention.	1	2	3	4	5	6
I forget a person's name almost as soon as I've been told it for the first time.	1	2	3	4	5	6
It seems I am "running on automatic," without much awareness of what I'm doing.	1	2	3	4	5	6
I rush through activities without being really attentive to them.	1	2	3	4	5	6
I get so focused on the goal I want to achieve that I lose touch with what I'm doing right now to get there.	1	2	3	4	5	6
I do jobs or tasks automatically, without being aware of what I'm doing.	1	2	3	4	5	6
I find myself listening to someone with one ear, doing something else at the same time.	1	2	3	4	5	6

	1	2	3	4	5	6
	Almost Always	Very Frequently	Somewhat Frequently	Somewhat Infrequently	Very Infrequently	Almost Never
I drive places on 'automatic pilot' and then wonder why I went there.					1	2 3 4 5 6
I find myself preoccupied with the future or the past.					1	2 3 4 5 6
I find myself doing things without paying attention.					1	2 3 4 5 6
I snack without being aware that I'm eating.					1	2 3 4 5 6

Positive and Negative Affect Schedule

PANAS Questionnaire

This scale consists of a number of words that describe different feelings and emotions. Read each item and then list the number from the scale below next to each word. Indicate to what extent you feel this way right now, that is, at the present moment *OR* indicate the extent you have felt this way over the past week (circle the instructions you followed when taking this measure)

1	2	3	4	5
Very Slightly or Not at All	A Little	Moderately	Quite a Bit	Extremely

_____ 1. Interested	_____ 11. Irritable
_____ 2. Distressed	_____ 12. Alert
_____ 3. Excited	_____ 13. Ashamed
_____ 4. Upset	_____ 14. Inspired
_____ 5. Strong	_____ 15. Nervous
_____ 6. Guilty	_____ 16. Determined
_____ 7. Scared	_____ 17. Attentive
_____ 8. Hostile	_____ 18. Jittery
_____ 9. Enthusiastic	_____ 19. Active
_____ 10. Proud	_____ 20. Afraid

Perceived Stress Scale- 4 Item

Instructions: The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate with a check how often you felt or thought a certain way.

1. In the last month, how often have you felt that you were unable to control the important things in your life?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

2. In the last month, how often have you felt confident about your ability to handle your personal problems?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

3. In the last month, how often have you felt that things were going your way?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

4. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

Wisconsin Inventory of Smoking Dependence Motives-68

Below are a series of statements about cigarette smoking. Please rate your level of agreement for each using the following scale:

	1	2	3	4	5	6	7
	Not True of Me At All						Extremely True of Me
1. I enjoy the taste of cigarettes most of the time.	1	2	3	4	5	6	7
2. Smoking keeps me from gaining weight.	1	2	3	4	5	6	7
3. Smoking makes a good mood better.	1	2	3	4	5	6	7
4. If I always smoke in a certain place it is hard to be there and not smoke.	1	2	3	4	5	6	7
5. I often smoke without thinking about it.	1	2	3	4	5	6	7
6. Cigarettes control me.	1	2	3	4	5	6	7
7. Smoking a cigarette improves my mood.	1	2	3	4	5	6	7
8. Smoking makes me feel content.	1	2	3	4	5	6	7
9. I usually want to smoke right after I wake up.	1	2	3	4	5	6	7
10. Very few things give me pleasure each day like cigarettes.	1	2	3	4	5	6	7
11. It's hard to ignore an urge to smoke.	1	2	3	4	5	6	7
12. The flavor of a cigarette is pleasing.	1	2	3	4	5	6	7
13. I smoke when I really need to concentrate.	1	2	3	4	5	6	7
14. I can only go a couple hours between cigarettes.	1	2	3	4	5	6	7
15. I frequently smoke to keep my mind focussed.	1	2	3	4	5	6	7
16. I rely upon smoking to control my hunger and eating.	1	2	3	4	5	6	7
17. My life is full of reminders to smoke.	1	2	3	4	5	6	7
18. Smoking helps me feel better in seconds.	1	2	3	4	5	6	7
19. I smoke without deciding to.	1	2	3	4	5	6	7
20. Cigarettes keep me company, like a close friend.	1	2	3	4	5	6	7
21. Few things would be able to replace smoking in my life.	1	2	3	4	5	6	7
22. I'm around smokers much of the time.	1	2	3	4	5	6	7
23. There are particular sights and smells that trigger strong urges to smoke.	1	2	3	4	5	6	7
24. Smoking helps me stay focussed.	1	2	3	4	5	6	7
25. Smoking helps me deal with stress.	1	2	3	4	5	6	7
26. I frequently light cigarettes without thinking about it.	1	2	3	4	5	6	7
27. Most of my daily cigarettes taste good.	1	2	3	4	5	6	7
28. Sometimes I feel like cigarettes rule my life.	1	2	3	4	5	6	7
29. I frequently crave cigarettes.	1	2	3	4	5	6	7
30. Most of the people I spend time with are smokers.	1	2	3	4	5	6	7
31. Weight control is a major reason that I smoke.	1	2	3	4	5	6	7
32. I usually feel much better after a cigarette.	1	2	3	4	5	6	7
33. Some of the cigarettes I smoke taste great.	1	2	3	4	5	6	7
34. I'm really hooked on cigarettes.	1	2	3	4	5	6	7
35. Smoking is the fastest way to reward myself.	1	2	3	4	5	6	7
36. Sometimes I feel like cigarettes are my best friends.	1	2	3	4	5	6	7

- | | | | | | | | |
|---|---|---|---|---|---|---|---|
| 37. My urges to smoke keep getting stronger if I don't smoke. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 38. I would continue smoking, even if it meant I could spend less time on my hobbies and other interests. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 39. My concentration is improved after smoking a cigarette. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 40. Seeing someone smoke makes me really want a cigarette. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 41. I find myself reaching for cigarettes without thinking about it. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 42. I crave cigarettes at certain times of day. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 43. I would feel alone without my cigarettes. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 44. A lot of my friends or family smoke. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 45. Smoking brings me a lot of pleasure. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 46. Cigarettes are about the only things that can give me a lift when I need it. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 47. Other smokers would consider me a heavy smoker. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 48. I feel a strong bond with my cigarettes. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 49. It would take a pretty serious medical problem to make me quit smoking. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 50. When I haven't been able to smoke for a few hours, the craving gets intolerable. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 51. When I do certain things I know I'm going to smoke. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 52. Most of my friends and acquaintances smoke. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 53. I love the feel of inhaling the smoke into my mouth. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 54. I smoke within the first 30 minutes of awakening in the morning. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 55. Sometimes I'm not aware that I'm smoking. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 56. I'm worried that if I quit smoking I'll gain weight. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 57. Smoking helps me think better. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 58. Smoking really helps me feel better if I've been feeling down. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 59. Some things are very hard to do without smoking. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 60. Smoking makes me feel good. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 61. Smoking keeps me from overeating. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 62. My smoking is out of control. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 63. I consider myself a heavy smoker. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 64. Even when I feel good, smoking helps me feel better. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 65. I reach for cigarettes when I feel irritable. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 66. I enjoy the sensations of a long, slow exhalation of smoke. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 67. Giving up cigarettes would be like losing a good friend. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 68. Smoking is the easiest way to give myself a lift. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

APPENDIX B IRB Documents

DATE: AUG 07, 2008

TO: David Wetter PHD MS BA
Box 243

FROM: Institutional Review Board IRB4
Office of Protocol Research
Box 198

SUBJECT: Full Committee Review Approval of 2004-0988, Entitled
"Group Therapy for Nicotine Dependence"

The above named and numbered protocol was reviewed in accordance with the Institutional Review Board (IRB) policy for Continuing Review of Research and the federal regulations governing human subjects research [45 CFR46.109(e) and 21 CFR 56.109(f)].

On JUL 31, 2008 the IRB4 approved the continuing review for this protocol based on the information provided. All research related activities may continue on this protocol.

Should you have any questions regarding this matter, please call the Office of Protocol Research at (713)792-2933 or send an email to IRB CONTINUING REVIEW@mdanderson.org.

Thank you for your cooperation.



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4799



September 18, 2009

MEMORANDUM FOR DR. ANDREW WATERS, PH.D., MEDICAL AND CLINICAL PSYCHOLOGY

SUBJECT: Uniformed Services University Institutional Review Board (FWA 00001628; DoD Assurance P60001) Approval regarding Human Subjects Research Protocol G172LA.

Congratulations! The initial review for your No More Than Minimal Risk human subjects research protocol G172LA, entitled "*Group Therapy for Nicotine Dependence*," was reviewed and approved for execution on Friday, September 18, 2009 by Edmund G. Howe III, M.D., J.D., Chairperson, Uniformed Services University IRB, under the provisions of 32 CFR 219.110(b)(1)Suppl. F(5). This approval will be reported to the full Uniformed Services University IRB scheduled to meet on Thursday, October 30, 2009.

This project is a sub-award of an ongoing University of Texas M.D. Anderson Cancer Center (MDACC) protocol, funded by the National Institutes of Drug Abuse. The MDACC protocol is a 3 group randomized clinical trial comparing the effectiveness of Mindfulness-Based Addiction Treatment) to Usual care and standard treatment for smoking cessation. Dr. Waters has been awarded a sub-contract to perform data analysis on the cognitive data collected under the MDACC protocol.

Note, prior to study initiation, the 2009 MD Anderson IRB approval paperwork must be provided to the IRB office.

Authorization to conduct protocol G172LA will automatically terminate on Friday, September 17, 2010. You are authorized to enroll up to 550 subjects in this study. If you plan to continue data collection or analysis beyond this date, IRB approval for continuation is required. Please submit a USU Form 3204A/B (application for continuing approval) to the IRB Office 60 days prior to the termination date. The IRB Office will attempt to assist you by sending you a reminder; however, submission of an application for continuation is your responsibility. Please note the termination date and the date for submission of your USU Form 3204A/B in your calendar!

You are required to submit amendments to this protocol, changes to the informed consent document (if applicable), adverse event reports, and other information pertinent to human research for this project to this office for review. No changes to this protocol may be implemented prior to IRB approval. If you have questions regarding this IRB action, or questions of a more general nature concerning human participation in research, please contact the undersigned at mstretch@usuhs.mil or (301) 295-0819.

Micah Stretch, M.A., J.D.
IRB Coordinator

cc: Chair, MPS
YPR/OSP
File

Institutional Review Board (IRB)
Continuing Review of Ongoing Clinical, Laboratory and Miscellaneous Protocols

Printable Version

Report Date: 02/19/10 Due Date: 03/05/10

The continuing review process is a requirement of this institution in compliance with federal regulations. The study Chairperson is responsible for updating the protocol status by providing the following information electronically to the Institutional Review Board for potential approval by the due date shown above. Direct your questions to the Office of Protocol Research at (713)792-2933 or send an email to IRB_ContinuingReview@mdanderson.org.

Protocol Number and Title: 2004-0988 - Group Therapy for Nicotine Dependence

Study Chairperson: David Wetter
 E-mail: dwetter@mdanderson.org
 NCI Support Grant Program: Behavioral and Health Disparities Research

For IRB4 Committee Review: 03/17/10
 Last Continuing Review: 05/28/09

APPROVED

03/11/10

Sponsor/Supporter:

Notes

⚠ Currently the co-investigator and/or collaborator list for this protocol exists as shown. Please submit a revision to the Office of Protocol Research if the list appears incorrectly.

Collaborators
 Click here

Co-investigators
 Click here

Current Protocol Status (Date)

03/16/05 Original IRB Approval
 06/24/09 Informed Consent

Waiver of informed consent: Yes No

04/11/05 Active (study in progress and accruing patients)

02/19/10 Request Close To New Patient Entry (no new patient accrual, but patients continuing on treatment or still alive for follow up)

Date last patient entered 02/19/10

Request Termination (no activity - all patients off study and no longer being followed)

NOTE: OFF DATE must be entered and a written summary must be attached that describes accrual, any toxicities and response data, and outcome(s) of research.

Is this a multicenter study? Yes No Maximum number of multicenter subjects approved 0

Maximum number of MDACC subjects approved 750 Registration required? Yes No Total accrual to date on CORE 642

The number of subjects where a translator was used during the informed consent process to verbally translate the consent document 0

Language(s) in which the consent was verbally translated:

Are all subjects off active intervention? Yes No
 If yes, are subjects in long term follow-up? Yes No

Total AEs reported 0 AEs since last review 0 Number of treatment related deaths 0

Give a summary of the toxicity profile? Not Applicable if n/a, explain why. (Printout of adverse events not acceptable)
 n/a

Give a summary of the response profile? Not Applicable if n/a, explain why.
 n/a